Clinical Evaluation of a New Foam Dressing With and Without Adhesive for the Local Management of Acute and Chronic Wounds

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Objectives:

1. To provide clinical experience in reducing patient pain using a foam dressing* with and without adhesive in acute and chronic wounds.

2. To provide clinical experience in clinical assessment of wound healing in acute and chronic wounds treated with a foam dressing* – with and without adhesive.

Statement of the Problem

Foam dressings are commonly used for moderate to heavily exuding chronic and acute wounds. When choosing an appropriate dressing, the potential for wound healing and pain reduction must be considered. Non-adherence, ease of application, and ease of removal of the dressing are all features that may contribute to these outcomes.

Methodology

This was an open-label, non-randomized evaluation of a foam dressing* newly introduced into the U.S. The study was conducted at 9 sites. Study subjects were selected from the general population of patients with acute and chronic wounds, for which the clinician found a foam dressing would be appropriate. Specific questions were asked to obtain the clinicians’ perception of performance characteristics of the products.

Results

Thirty-five wounds had the foam* applied (21 chronic, 14 acute). Clinician perception of the ease of application, adherence to wound, and pain during removal of the foam dressing was assessed.

Conclusion

The new foam* was easily applied and removed with minimal to no adhesion to the wound bed. This may decrease patient pain during dressing removal and help promote the wound healing process in the chronic and acute wounds observed in this product evaluation.

* Product used was UrgoCell Adhesive and UrgoCell Non-adhesive (Laboratoires URGO, Dijon, France) marketed in the U.S. as Restore Adhesive Foam Dressing with TRIACT Technology and Restore Non-Adhesive Foam Dressing with TRIACT Technology by Hollister Wound Care LLC.
**Study Objectives**

- The primary objective of this product evaluation was to obtain the perception of the users about characteristics of the adhesive foam and non-adhesive foam dressings* featuring Technology Lipido Colloid (TLC—known in the U.S. as TRIACT Technology), specifically with the following parameters:
  - Ease of application of the dressing
  - Adherence of the dressing to the wound
  - Pain during removal of the dressing
- The secondary objective was to obtain an overall impression of time and resources required to use the adhesive foam and non-adhesive foam dressings

**Study Design**

- Open-label, non-randomized, uncontrolled product evaluation
- 9 sites—between 3 and 13 subjects were recruited at each site
- Eligibility of subjects defined as those with acute or chronic wounds for whom foam dressings were appropriate
- Each Institution’s practice and product instructions were adhered to
- Subjects were followed until one of the following occurred:
  - Use of the foam dressing was no longer appropriate
  - Wound healed
  - Four weeks had passed
- Specific questions were asked in order to obtain each clinician’s perception of the performance characteristics of the foam dressings

**Results**

A total of thirty-five (35) wounds were treated with the adhesive foam or non-adhesive foam dressings. Table 1 summarizes the demographics of the subjects for which the foam dressings were used.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Age, yrs (SD)</th>
<th>Chronic Wound</th>
<th>Acute Wound</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>35</td>
<td>57.9 (17.1)</td>
<td>23</td>
<td>12</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>14</td>
<td>60.3 (14.3)</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>21</td>
<td>56.4 (19.0)</td>
<td>12</td>
<td>9</td>
</tr>
</tbody>
</table>

**Types of Wounds Treated with Adhesive Foam and Non-Adhesive Foam Dressings**

- 5 Pressure Ulcers
  - 3 Stage II ulcers
  - 1 Stage III ulcer
  - 1 Unstageable ulcer
- 10 Venous Ulcers
- 1 Lymphedema
- 2 Traumatic - Chronic
- 6 Postoperative
  - 5 acute
  - 1 chronic
- 1 Skin Tear
- 1 Shingles
- 1 Gastrostomy-tube Site
- 1 Spider Bite
- 1 Partial Thickness Blister
- 6 Skin Graft Donor Sites
Figure 1. Clinician perception on the ease of application of the adhesive foam and non-adhesive foam dressings.

**Ease of Application of Foam Dressing**
- Very Easy: 14%
- Easy: 3%
- Difficult: 83%

Figure 2. Clinician perception of the conformability of the foam dressings to the wound.

**Conformability of the Foam to the Wound**
- Very Good: 20%
- Good: 3%
- Poor: 77%

Figure 3. Clinician perception on the amount of bleeding present with the removal of the foam dressings.

**Bleeding Upon Removal of the Foam Dressing**
- None: 3%
- Minimal: 97%

Figure 4. Clinician perception on the adherence of the foam dressings to the wound.

**Adherence of the Foam Dressing to the Wound**
- None: 14%
- Minimal: 3%
- Moderate: 16%
- Severe: 75%

Figure 5. Clinician assessment of maceration present associated with use of the foam dressings.

**Maceration Present with Foam Dressing Use, N=32**
- None: 6%
- Minimal: 3%
- Moderate: 18%
- Severe: 75%

Figure 6. Clinician perception of the ease of removal of the foam dressings.

**Ease of Removal of the Foam Dressing, N=32**
- Very Easy: 3%
- Easy: 97%
Figure 7. Perceived pain associated with the removal of the foam dressings.

Pain During Removal of the Foam Dressing, N=31

- None: 3%
- Minimal: 97%

Figure 9. Clinician Overall Recommendation to Use the Foam Dressings.

Clinician Recommends Use of the Foam Dressings

- Strongly Agree: 43%
- Agree: 51%
- Disagree: 6%
- Strongly Disagree: 6%

Figure 8. Amount of Wound Exudate During the Use of the Foam Dressings

Amount of Wound Exudate During the Use of the Foam Dressing, N=32

- None: 22%
- Minimal: 31%
- Moderate: 34%
- Severe: 13%

Conclusion

The new adhesive foam and non-adhesive foam dressings* were easily applied and removed with minimal to no adhesion to the wound bed. This may decrease patient pain during dressing removal and help promote the wound healing process in the chronic and acute wounds observed in this product evaluation.

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