A Pilot Study of a New Low Air Loss Treatment Surface in the Critical Care Setting

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Introduction

Critical care patients have a high incidence of nosocomial and community-acquired pressure ulcers. Pressure redistributing surfaces are an important part of prevention and treatment of pressure ulcers. This study evaluated a new pressure ulcer treatment and prevention mattress surface which electronically senses high pressure zones and applies pressure to non-loaded areas which redistributes pressure, maximizing immersion and pressure redistribution.

Study Design

The study is an open label, prospective, observational natural history study, using a cross-sectional convenience sample. A total of 30 subjects meeting the defined inclusion criteria were placed on the Envision® surface for a minimum of 3 days, and a maximum of 7 days. The study endpoints include the following:

- Voluntary subject withdrawal
- Completion of 3 to 7 continuous days on the Envision® surface

Exclusion criteria: Subjects will be excluded from the study if they meet any of the following criteria:

- Subject weighs between 70 and 400 pounds.
- Subject or legal representative is willing and able to provide voluntary consent for study participation.
- Subject or legal representative is not willing to sign the consent for study participation.
- Subject or legal representative or subject is not able to consent for study participation.
- Physician, subject or subject’s representative declines to provide consent for study participation.
- Voluntary subject withdrawal.

Conclusions

With the National Healthcare spotlight on nosocomial pressure ulcers, the introduction of a new pressure redistribution treatment surface to a critical care setting is judicious. By the numbers the Envision mattress performed favorably in the following criteria:

- Decrease in Wound size 5% Area (cm²)
- Decrease in Ulcer Volume 41% (cm³)
- Staff satisfaction rating of 4.1 on a 5 point scale

To further assess the effectiveness of the mattress in this high acuity population a comparison study will be required.

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Manager, Clinical Research, Hill-Rom Inc.
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Methods

Inclusion criteria: For inclusion, subjects must meet all of the following criteria:

- Subjects admitted to the critical care
- Subjects are identified as being at high risk for pressure ulcer development (Braden ≤ 14)
- or who have existing pressure ulcers of any stage were sought for study participation.
- Subject or legal representative is willing and able to provide voluntary consent for study participation.
- Subject weighs between 70 and 400 pounds.
- Subject is expected to remain on the Envision surface for at least 3 days (this is a subjective assessment).

Exclusion criteria: Subjects will be excluded from the study if they meet any of the following criteria:

- Subject has an unstable spine.
- Subject requires a pulmonary treatment mattress surface.
- Physician, subject or subject's representative declines to provide consent.

Subject Demographics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Outcome</th>
<th>Parameter</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Mean ± SD)</td>
<td>174 ± 32 pounds</td>
<td>Height (Mean ± SD)</td>
<td>66 ± 4 inches</td>
</tr>
<tr>
<td>Age (Mean ± SD)</td>
<td>23 – 88 years</td>
<td>Ethnicity</td>
<td>African American</td>
</tr>
<tr>
<td>Gender Males/Females</td>
<td>14/16 (47%/33%)</td>
<td></td>
<td>60 – 73.6 inches</td>
</tr>
<tr>
<td>Braden Score</td>
<td>12 ± 1.6</td>
<td></td>
<td>20/30 (66%)</td>
</tr>
</tbody>
</table>

Summary of Medical Status

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Outcome</th>
<th>Parameter</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary Incontinence</td>
<td>27/30 (90%)</td>
<td>Neurologic Impairment</td>
<td>4/30 (13%)</td>
</tr>
<tr>
<td>Braden Score Initial (Mean ± SD)</td>
<td>8 – 14</td>
<td>Normal</td>
<td>23/30 (77%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Some Impairment</td>
<td>1/30 (33%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Common Pressure</td>
<td>1/30 (33%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quadruple pressure</td>
<td>1/30 (33%)</td>
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Results

1. 30 patients were enrolled.
2. Average LOS was 6 days.
3. Average Braden Pressure ulcer risk score of 12 ± 1.6 SD (range 8–14)
4. 27/30 (90%) had Urinary incontinence
5. 24/30 (80%) were incontinent of stool
6. Neurologic Impairment
   - Normal - 4/30 (13%)
   - Some Impairment - 23/30 (77%)
   - Common Pressure - 1/30 (33%)
   - Quadruple Pressure - 1/30 (33%)
7. 33 existing pressure ulcers admitted to the study
8. Stages of the ulcers (by NPUAP Staging system) were,
   - 15 Stage II
   - 9 Stage III
   - 4 Stage IV
   - 4 Untreatable
   - 1 Deep Tissue Injury
9. Ulcers decreased in volume an average of 41% if all ulcers are considered, and 43% if one patient who became significantly more hypoxic is excluded.
10. Area changes were 0.09 cm²/day if all patients are considered, and the hypoxic patient is excluded, 0.16 cm²/day.
11. Caregivers rated the surface 4.1 on a 5 points scale (5 = extremely satisfied)

Change in Ulcer Area

<table>
<thead>
<tr>
<th>Change in Ulcer Area</th>
<th>All Patients</th>
<th>Hypoxic Patient Exclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Patients</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>All Patients/All Ulcers</td>
<td>41%</td>
<td>43%</td>
</tr>
</tbody>
</table>

Change in Ulcer Volume

<table>
<thead>
<tr>
<th>Change in Ulcer Volume</th>
<th>All Patients/All Ulcers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume Initial</td>
<td>1.41%</td>
</tr>
<tr>
<td>Volume Final</td>
<td>0.57%</td>
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*Manager, Clinical Research, Hill-Rom Inc.