An open, prospective, randomized, comparative volunteer trial to compare the performance of a silicone gel adhesive composite hydrocellular foam dressing (SGA-CHF†) compared to two alternative silicone gel adhesive dressings

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Introduction
The silicone gel adhesive composite hydrocellular foam (SGA-CHF) dressing is an exudate management wound dressing to be used on moderate to highly exuding wounds. The multi-layered dressing is designed to be highly absorbing and contains fluid retaining materials and a masking layer to hide the exudate strike through whilst also functioning as additional protection and cushioning within the dressing.

Aim
The study (conducted on 100 volunteers) assessed the SGA-CHF dressings compared to an Alternative Silicone Gel Adhesive (ASGA)* and Bilamine Island Silicone** (BIS) dressings in terms of dressing retention over a period of 7 days. The primary objective of the study was to compare the SGA-CHF dressing to the two alternative silicone gel adhesive dressings in terms of dressing lift to pad at day 3. Assessments were made to compare the performance of SGA-CHF dressing in terms of dressings in place and integrity of the pad (bunching of the pad).

Method
Volunteers had dressings randomised across 4 sites on the thighs. Volunteers returned on days 1 and 3 for dressing assessments and day 7 for dressing removal.

Demographics
100 volunteers were recruited. The mean age of volunteers was 42 years (range 23-61) with a gender distribution of 33% female and 66% male.

Results
Dressing lift to pad
Dressing lift to the pad was defined as all dressings that had either become detached or were partially adhered but had lifted to the pad and therefore compromised.

• SGA-CHF vs. ASGA
There was significant evidence that fewer SGA-CHF dressings lifted to the pad compared to ASGA dressings at day 1 (23% vs. 36%, p=0.042), day 3 (40% vs. 56%, p=0.016) and day 7 (55% vs. 75%, p=0.002) (see figure 1).

• SGA-CHF vs. BIS
There was significant evidence that fewer SGA-CHF dressings lifted to the pad compared to BIS dressings at day 1 (23% vs. 80%, p<0.001), day 3 (40% vs. 96%, p<0.001) and day 7 (55% vs. 75%, p<0.001) (see figure 2).

Dressing lift to pad
Dressings in place included any dressing than did not have greater than 50% dressing lift (or was not present), or a severely soaked/hanging dressing which would be regarded as a failed dressing

Table 1: Percentage of dressings experiencing bunching of the pad

<table>
<thead>
<tr>
<th></th>
<th>ASGA</th>
<th>SGA-CHF</th>
<th>% Difference</th>
<th>Lower</th>
<th>Upper</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison</td>
<td></td>
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<td></td>
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<tr>
<td>SGA-CHF - ASGA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>57%</td>
<td>100%</td>
<td>-43%</td>
<td>0.127</td>
<td>0.263</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>43%</td>
<td>0%</td>
<td>+43%</td>
<td>0.127</td>
<td>0.263</td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>5</td>
<td>100</td>
<td>95%</td>
<td>0.250</td>
<td>0.450</td>
<td></td>
</tr>
</tbody>
</table>

The green cell in cross tabulations shows incidences where SGA-CHF performed better than ASGA. Conversely, the red cells show incidences where SGA-CHF performed worse. The grey cells indicate no difference between the dressings.

Conclusion
SGA-CHF dressing was shown to be superior to ASGA and BIS in terms dressing lifting to the pad and the dressings in place after 1, 3 and 7 day wear. The SGA-CHF dressing also demonstrated superiority compared to ASGA in terms of dressing integrity (measured by bunching of the pad after 1 day wear). There was no evidence of a difference when comparing SGA-CHF to BIS in terms of dressing integrity after day 1.

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