Clinical and Laboratory Methods for Evaluating Pressure Sensitive Adhesives for Skin Contact Medical Applications

• Presented by Michael R. Krejsa, Ph.D., Henkel Corporation, Technical Service Manager
Presentation Outline

• Background
• Project Goal
• Lab testing approaches
• Clinical trial approaches
• Results and correlations between lab testing and clinical trials
• Conclusions
• Acknowledgements
Background

• Pressure sensitive adhesives (PSA’s) are used in a wide range of skin contact medical application with a range of requirements
  • Wear times from short (>1 day) to long (up to 21 days)
  • Wide range of facestocks from highly conformable to rigid materials

• Historic approach is lab testing for screening followed by end use application testing
  • Lab testing easy to do, not a good predictor of application performance
  • End use testing is expensive and time consuming
Project Goal

• To develop in house clinical trial protocols for multiple applications using a range of constructions
• Implement more application appropriate lab screening methods for skin contact medical PSA products
• Using the improved lab screening methods and the in house clinical trial protocols, identify key adhesive parameters for a variety of skin contact medical PSA applications
Lab Screening Approaches

• Lab screening performed on synthetic skin substitute: VITRO-SKIN N19 model for human back skin
  • Modeled to match topography, pH, critical surface tension, ionic strength
• Peel testing (20 minutes, 24 hours): stainless steel, VITRO-SKIN
• Shear testing from stainless steel
• Moisture Vapor Transmission Rate (MVTR) testing using inverted cup method
Clinical Trial Protocol Development

• Identify what are the critical requirements for the specific application
• Utilize an appropriate construction
• Include all relevant tests to ensure adhesive and construction is appropriate for skin contact
Clinical Trials: Low Trauma

- Critical requirements
  - Minimal pain upon removal
  - Acceptable wear over 1 day
  - Include positive and negative controls

- Construction:
  - 1” by 3” standard wound care design
  - Facestock: 1.2 mil breathable polyurethane (PU) film

- Other requirements:
  - Little to no irritation in test area
  - Little to no adhesive transfer or residue upon removal
Clinical Trials: Long Wear

• Critical requirements
  • Maximum possible wear with various constructions
  • Use of appropriate facestocks for market segment
  • Include positive control

• Construction:
  • 1” by 3” standard wound care design
  • Facestocks: 1.2 mil breathable polyurethane (PU) film, spun lace polyester non-wovens at 1.3 oz/yd² and 2.4 oz/yd²

• Other requirements:
  • Little to no irritation, adhesive transfer or residue upon removal
Clinical Trials: Test Procedure

Examples of test constructions and locations on body for testing
Clinical Trials: Wear Evaluation

• Testing criteria for wear
• Short wear evaluated at 1 day
• Long wear evaluated at Days 4, 7, 11, 14, 18, 21 (apply and remove on a Monday, review Fridays and Mondays)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Wear (Adhesion) Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Test strip off</td>
</tr>
<tr>
<td>1</td>
<td>Test strip almost off (hanging)</td>
</tr>
<tr>
<td>2</td>
<td>¾ of test strip off</td>
</tr>
<tr>
<td>3</td>
<td>½ of test strip off</td>
</tr>
<tr>
<td>4</td>
<td>¼ of test strip off</td>
</tr>
<tr>
<td>5</td>
<td>3 to 4 edges lifted</td>
</tr>
<tr>
<td>6</td>
<td>1 to 2 edges lifted</td>
</tr>
<tr>
<td>7</td>
<td>All corners adhering firmly</td>
</tr>
</tbody>
</table>
Clinical Trials: Pain Evaluation

- Testing criteria primarily for low trauma applications
- Based on common medical industry practices
- Pain rating varies season to season, person to person: positive and negative controls are critical!
Results: Low Trauma

• Clinical Trial Results
  • Minimum acceptable wear rating is 5
  • Silicone is “gold standard” for this market segment
  • Used aggressive solvent acrylic as negative control

<table>
<thead>
<tr>
<th>Adhesive</th>
<th>Pain Rating (0-10)</th>
<th>Wear Rating (0-7)</th>
<th>MVTR (g/m2/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicone (Positive Control, 8 mil)</td>
<td>1.2</td>
<td>5.6</td>
<td>247</td>
</tr>
<tr>
<td>Hot Melt A</td>
<td>1.6</td>
<td>4.6</td>
<td>12</td>
</tr>
<tr>
<td>Solvent Acrylic B</td>
<td>1.7</td>
<td>6.5</td>
<td>379</td>
</tr>
<tr>
<td>Emulsion Acrylic C</td>
<td>1.9</td>
<td>6.7</td>
<td>1000</td>
</tr>
<tr>
<td>Solvent Acrylic D (Negative Control)</td>
<td>3.0</td>
<td>7.0</td>
<td>510</td>
</tr>
<tr>
<td>Hot Melt E</td>
<td>0.2</td>
<td>0.8</td>
<td>20</td>
</tr>
</tbody>
</table>
Results: Low Trauma

• VITRO-SKIN adhesion is good predictor of pain upon removal in short wear, low trauma application
Results: Long Wear Clinical Trial

• Wear time ranges obtained for each adhesive
Results: Long Wear

<table>
<thead>
<tr>
<th>Adhesive</th>
<th>SS Peel, 20 min (ozf/in)</th>
<th>Shear, 4.4 psi (h)</th>
<th>MVTR (g/m2/day)</th>
<th>Wear, PU</th>
<th>Wear, NW1</th>
<th>Wear, NW2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvent Acrylic A</td>
<td>73</td>
<td>1.9</td>
<td>372</td>
<td>Green</td>
<td>Yellow</td>
<td>Red</td>
</tr>
<tr>
<td>Solvent Acrylic B</td>
<td>76</td>
<td>0.3</td>
<td>510</td>
<td>Yellow</td>
<td>Red</td>
<td>Red</td>
</tr>
<tr>
<td>Solvent Acrylic C</td>
<td>62</td>
<td>10</td>
<td>515</td>
<td>Yellow</td>
<td>Red</td>
<td>Red</td>
</tr>
<tr>
<td>Solvent Acrylic-Rubber Hybrid D</td>
<td>125</td>
<td>120</td>
<td>97</td>
<td>Green</td>
<td>Yellow</td>
<td>Red</td>
</tr>
<tr>
<td>Solvent Acrylic E</td>
<td>98</td>
<td>2.4</td>
<td>454</td>
<td>Yellow</td>
<td>Red</td>
<td>Red</td>
</tr>
<tr>
<td>Solvent Acrylic F</td>
<td>50</td>
<td>168</td>
<td>379</td>
<td>Red</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Meets 21 day wear requirements
- Below 21 day wear requirements
- Significantly below 21 day wear requirements

- SS shear, peel do not predict wear
- MVTR shows negative correlation with wear
### Results: Long Wear

VITRO-SKIN adhesion correlates with wear for conformable PU facestock

<table>
<thead>
<tr>
<th>Adhesive</th>
<th>VS Peel, 20 min, PU (ozf/in)</th>
<th>VS Peel, 20 min, NW1 (ozf/in)</th>
<th>VS Peel, 20 min, NW2 (ozf/in)</th>
<th>Wear, PU</th>
<th>Wear, NW1</th>
<th>Wear, NW2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solvent Acrylic A</td>
<td>36</td>
<td>24</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solvent Acrylic B</td>
<td>33</td>
<td>25</td>
<td>24</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solvent Acrylic C</td>
<td>20</td>
<td>28</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solvent Acrylic-Rubber Hybrid D</td>
<td>43</td>
<td>68</td>
<td>55</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solvent Acrylic E</td>
<td>36</td>
<td>22</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solvent Acrylic F</td>
<td>23</td>
<td>18</td>
<td>21</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Meets 21 day wear requirements
- Below 21 day wear requirements
- Significantly below 21 day wear requirements
Results: Long Wear

• VITRO-SKIN adhesion correlates with wear for conformable PU facestock
Results: Long Wear

- MVTR shows negative correlation with wear
Results: Long Wear

- Additional facestock showing negative correlation between MVTR and wear
Conclusions

• Clinical trials continue to be the “gold standard” for predicting end use application suitability

• For short wear applications, adhesion to VITRO-SKIN synthetic skin correlates to pain upon removal

• For long wear applications, adhesion to VITRO-SKIN with conformable PU facestock correlates to long wear performance

• For more rigid non-woven facestocks, adhesion to VITRO-SKIN does not correlate well to wear performance, as other factors come into play.

• MVTR is not a good predictor of wear
The author would like to acknowledge the work of the many individuals who have worked on making this a successful project:

• A special acknowledgement goes to Allison Luciano for all of her input, suggestions, comments and key insights!

• Kate Layser for her support from the Marketing side.

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