Wound Closure Strength and Flexibility Comparisons of Topical Skin Adhesives

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BACKGROUND: Five topical skin adhesives are currently FDA-approved in the United States as Class II medical devices. Dermabond® and SurgiSeal™ are 2-octyl cyanoacrylates (OCA) and Histoacryl®, Indermil®, and LiquiBand™ are n-butyl cyanoacrylates (BCA). Comparisons of all five products to measure wound closure strength and flexibility have not previously been completed.

STUDY DESIGN: Five different brands of cyanoacrylate topical skin adhesive were compared with two tests:

1) Wound Closure Strength: Incisions made in pig skin were closed by each of the five products, according to each product's instructions. The incisions were then pulled apart to record the force required to separate the incision as the wound closure strength. Multiple data points were collected for each skin adhesive and averaged to achieve an average wound closure strength, which is measured in pounds.

2) Flexibility: Polymer films of each of the five products were prepared on synthetic skin and bent over three sized mandrel bend rods (½", ¼", ⅛")¹. Multiple data points were collected for each skin adhesive for each size. Whether or not the adhesive cracked during the bending process was recorded.

RESULTS: In the wound closure strength test, SurgiSeal received the highest average score of 4.76 lbs., followed by Histoacryl (4.10 lbs.), Dermabond (3.64 lbs.), Indermil (2.70 lbs.) and LiquiBand (1.56 lbs.).

The results of the flexibility test were as follows: Both SurgiSeal and Dermabond had no cracks on any of the mandrels. LiquiBand cracked on 50% of the ½” rods, 80% of the ¼” rods, and 90% of the ⅛” rod. Histoacryl cracked on 90% of the ½” rods and 100% of the ¼” and ⅛” rods. Indermil cracked on 100% of each of the three sized of rods.

CONCLUSIONS: Wound closure strength measures the capability of a topical skin adhesive to maintain approximation of a wound despite the pressure on the wound. Both SurgiSeal and Histoacryl earned high strength scores. While it was previously thought that OCA products have greater wound closure strength than those of BCA products², these tests demonstrate that Histoacryl, a BCA product, measured stronger than Dermabond, an OCA, in wound closure strength.

The type of cyanoacrylate determines flexibility: OCA products, due to a longer polymer chain, have demonstrated greater flexibility than BCA products. SurgiSeal and Dermabond have both demonstrated superior flexibility in terms of the ability of the adhesive to not crack when subjected to bending. From a clinical standpoint, OCA products will provide a more consistent coverage to a wound, especially those subject to bending and/or flexing.

¹ Flexibility was measured with the Mandrel bend test following American Society for Testing and Materials (ASTM) D4388.
WOUND CLOSURE STRENGTH

Objective: To evaluate the wound closure strength utilizing in vitro studies for the topical skin adhesives:
- Dermabond® Topical Skin Adhesive (OCA)
- Histoacryl® Topical Skin Adhesive (BCA)
- Indermil® Tissue Adhesive (BCA)
- LiquiBand™ Topical Skin Adhesive (BCA)
- SurgiSeal™ Topical Skin Adhesive (OCA)

Apparatus: Mark-10 Tensiometer – Tensile strength tester

Method: Incisions of one inch in length were made on the middle of the pig skin. The incisions were then closed by different wound closure products according to their specific instructions. The disrupting forces of the closed incisions were then measured by a Mark-10 tensiometer at 25 mm/min.

Procedure: 1) Prepare a pig skin (2 x 4 inch) by wiping the surfaces of the skin with sterile gauze saturated with isopropanol and make sure to remove all oily substances from the pig skin.
2) Then wipe the surface with sterile gauze to remove isopropanol.
3) An incision of one inch in length is made at the mid-section of the sample, as shown in Figure 1.

4) After the incisions were closed by applying the adhesive, the pig skins were mounted onto a Mark-10 tensiometer to measure the wound closure strength of the different products. The disrupting forces were recorded when the incision was pulled apart, known as the wound closure strength. Figure 2 shows a picture of the incision closed by an adhesive and its opening by being pulled apart.
WOUND CLOSURE STRENGTH (CONT’D)

Figure 2. An incision closed by LiquiBand (left) and its opening by being pulled apart on the Mark-10 tensiometer.

5) The wound closure strength tests were repeated five or ten times for each product, and the results are summarized in the Results section.

Results:

<table>
<thead>
<tr>
<th>Brand</th>
<th>Average Wound Closure Strength (lbs.)</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermabond</td>
<td>3.64</td>
<td>0.83</td>
</tr>
<tr>
<td>Histoacryl</td>
<td>4.10</td>
<td>0.47</td>
</tr>
<tr>
<td>Indermil</td>
<td>2.70</td>
<td>0.62</td>
</tr>
<tr>
<td>LiquiBand</td>
<td>1.56</td>
<td>0.44</td>
</tr>
<tr>
<td>SurgiSeal</td>
<td>4.76</td>
<td>0.70</td>
</tr>
</tbody>
</table>
FLEXIBILITY

Objective: To evaluate the flexibility utilizing the Mandrel bend test based on ASTM method D4338-97 for the topical skin adhesives:
- Dermabond® Topical Skin Adhesive (OCA)
- Histoacryl® Topical Skin Adhesive (BCA)
- Indermil® Tissue Adhesive (BCA)
- LiquiBand™ Topical Skin Adhesive (BCA)
- SurgiSeal™ Topical Skin Adhesive (OCA)

Definitions: Fixed test mandrel.

Method:
A tattoo practice skin (synthetic skin) coated with a film of Dermabond, Histoacryl, Indermil, LiquiBand, or SurgiSeal. The skin is folded to form an inverted U-shaped angle over the mandrel maintaining intimate contact with the non-adhesive side. Using a fresh specimen for each test, the test is repeated with progressively smaller diameter mandrels.

Procedure:
1) Apply adhesive onto tattoo practice skin with a dimension of 2 x 4 inches.
2) Store the test specimens and test apparatus at the test conditions for 24 hours.
3) Run the tests in the same environment used to condition the test specimens and test apparatus.
4) Put the largest diameter mandrel in the horizontal operating position in the test frame.
5) Grasp the test specimen between the thumb and forefinger of one hand, with the longest dimension between the fingers. For low-temperature testing, use cotton work gloves to insulate the test specimens from the warm fingers.
6) Lay the flat steel (or other support substrate) of the test specimen tangentially at right angles to the longitudinal axis of the test mandrel.
7) Fold the test specimen with the adhesive side opposite to the mandrel to form an inverted U-shaped angle over the mandrel maintaining intimate contact with the mandrel.
8) Observe and record a fracture, crazing, or cracking of the adhesive film visible to the naked eye. This can occur at any time during the bending of the adhesive test specimen over the mandrel.
9) Fold a fresh specimen of the next smaller diameter mandrel.
10) Repeat the test five or ten times, using fresh specimens, on three mandrels with different diameters.

Results:

<table>
<thead>
<tr>
<th>Brand</th>
<th>% Cracks with ½” Diameter Mandrel</th>
<th>% Cracks with ¼” Diameter Mandrel</th>
<th>% Cracks with ⅛” Diameter Mandrel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermabond</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Histoacryl</td>
<td>90%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Indermil</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>LiquiBand</td>
<td>50%</td>
<td>80%</td>
<td>90%</td>
</tr>
<tr>
<td>SurgiSeal</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
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