Effectiveness of
INDERMIL® TISSUE ADHESIVE
as a Microbial Barrier

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OBJECTIVE

The purpose of this study was to demonstrate that Indermil® Tissue Adhesive will not allow penetration of a variety of microorganisms that have been shown to cause infections.

BRIEF DISCUSSION ON SURGICAL SITE INFECTIONS

Microbial site infection is a necessary precursor of surgical site infections. The risk of infection is equal to the amount of bacteria present (dose) multiplied by the virulence of the bacteria and divided by the resistance of the host.³ Anything that increases the presence of bacteria or decreases the immune response of the patient increases the risk for surgical site infection. The number of bacteria required to produce an infection is lower if a foreign body is present. Foreign bodies include sutures. One study demonstrated as few as 100 staphylococci per gram of tissue on silk sutures can cause a wound infection. In contrast, without a foreign body present, estimates are 10,000 microorganisms per gram of tissue are required to cause infection.²

IN-VITRO STUDY DESIGN

This study was undertaken to demonstrate that Indermil® Tissue Adhesive is an effective barrier against the penetration of clinically relevant microorganisms in an in-vitro model. By using a pH sensitive dye in the underlying agar media, the penetration of microorganisms and/or their acidic metabolic by-products (when bacteria grow they produce acid) can be detected. The dye used, bromocresol, will change from purple to yellow in the presence of these metabolic acid by-products. If Indermil® Tissue Adhesive is an effective microbial barrier then the application of a thin film of Indermil® to the surface of the agar should prevent the bacteria and their by-products from coming in contact with the agar, thereby preventing the color change from purple to yellow. Indermil® was applied sparingly in a single application as instructed in the Indermil® Product Insert and formed approximately a 1mm thickness thin film over the agar media.
MICROBIAL CULTURES

Four commonly infectious organisms were used, plus a skin bacterium, staphylococcus epidermidis, which is known to cause nosocomial skin infections.

<table>
<thead>
<tr>
<th>TEST ORGANISM</th>
<th>CHALLENGE POPULATION</th>
<th>NUMBER TESTED</th>
<th>NUMBER SHOWING PENETRATION AFTER 7 DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. ALBICANS</td>
<td>$4.5 \times 10^5$</td>
<td>96</td>
<td>0</td>
</tr>
<tr>
<td>S. AUREUS</td>
<td>$1.1 \times 10^7$</td>
<td>96</td>
<td>0</td>
</tr>
<tr>
<td>S. EPIDERMIDIS</td>
<td>$1.4 \times 10^6$</td>
<td>96</td>
<td>0</td>
</tr>
<tr>
<td>E. COLI</td>
<td>$1.1 \times 10^7$</td>
<td>96</td>
<td>0</td>
</tr>
<tr>
<td>P. AERUGINOSA</td>
<td>$7.7 \times 10^6$</td>
<td>96</td>
<td>0</td>
</tr>
</tbody>
</table>

The stock cultures were prepared by inoculating growth media and incubating for 18-24 hours at 30-35°C. The maximum number of each organism grown during this period was then inoculated over the polymerized Indermil® Tissue Adhesive film.

Indermil® Tissue Adhesive was challenged with test organisms ranging in population from 450,000 to 11 million microorganisms. These challenge populations were multiples of 45 to 1,100 times the 10,000 microorganisms per gram of tissue that are required to cause infection without a foreign body present.²
TEST RESULTS: (cont’d)

Controls demonstrated that the sensitivity of the test methods would only require the penetration of a single microorganism to show a positive result (changed agar from purple to yellow) within 48 hours. Since no Indermil® covered agar media changed colors, the results demonstrate that Indermil® Tissue Adhesive was effective in blocking 100% of the microorganisms from penetrating, over the test period.

CONCLUSION:

Indermil® Tissue Adhesive provided an effective microbial barrier in all 480 challenges. The data show that the test is sensitive enough to detect one organism contacting the agar media after 48 hours and that Indermil® Tissue Adhesive is capable of preventing bacterial penetration when challenged with greater than $4.5 \times 10^5$ organisms. FDA approval as a microbial barrier for lacerations and skin incisions was granted to Indermil® Tissue Adhesive based on these in-vitro study results.
