Evaluation of Wear Time for Various Tapes on Human Volunteers: 21-day Study

Authors: Marcia Cartier, Clinical Research Associate and Graham Smith, Biostatistician
3M Medical Materials & Technologies, 3M Healthcare

Introduction
Medical adhesives can be used in a variety of applications, such as securing wearable sensors, health monitors or other medical devices. Depending on the user population, some adhesives – typically in tape form - need to be gentle for fragile skin, or able to adhere even in moist conditions. Depending on the application, some tapes need to be more flexible or stretchable to better conform to body contours. Different properties can be obtained by varying the backing material and the type of adhesive used. For these reasons, a variety of tapes with different properties exist and it is important to choose the correct construction for the desired application.

This study was intended to determine the approximate wear time of five commercially available and seven investigational tapes on non-compromised skin of healthy volunteers. The objective of the study was not to imply that all tapes would remain attached to the skin for 21 days, but rather to develop a better understanding of the likely wear time of each of the tapes (survival) in this study. This paper shares data on the five commercially available products evaluated in this study. The acrylate-based adhesives used in these tapes were subjected to ISO 10993 testing for body contact of up to 30 days for a surface device on intact skin.

Subjects and Methods
This Institutional Review Board (IRB) approved study was performed in controlled conditions on the backs of 24 healthy volunteers. One subject chose to drop from the study on Day 20 due to a personal scheduling conflict. This study was not listed on ClinicalTrials.gov.

The study was split into two arms each having 12 subjects wearing six unique tapes. Subjects were asked to refrain from using moisturizers or other skin contacting materials on the test sites during the study and for 24 hours prior to the initial study visit. They were also asked to refrain from taking antihistamines within 48 hours of the study and for the duration of the study as it could mask skin changes. If an excessive amount of hair existed on the test sites, the area was clipped prior to the initiation of the study to ensure good sample-skin contact. Swimming and like activities were restricted for the 21 days. Front facing showers were requested for all subjects.

The skin was washed and one inch by three inch samples were applied on the subjects’ backs according to a randomized rotational order (3 replicates of 6 different tapes on each subject). The layout of the samples is illustrated in Figure 3. The subjects were instructed to keep a diary of showers (time and duration) and activities, as well as any event of tape loss. Subjects maintained regular activities during the entire 21 days.

One replicate was scheduled to be removed from each subject at Day 10 for each sample. This was to be removed from the lower half of the back so long as there were no previous failures of that sample on the upper half of the back. Therefore, the sample size drops at Day 10 as a function of the protocol. This was to observe the skin condition at the midpoint of the study.

Pain upon removal was noted at both the midpoint of 10 days and the end point of 21 days. Subjects were asked to rate their pain on a Visual Acuity Scale with a numeric pain index from 0 to 110.
Statistical Methods
Wear time or time to sample removal was examined using the appropriate survival methods that took censoring and study design into account. The Kaplan-Meier survival curve was created for each sample in the study, but direct comparisons between products were not necessary. The primary objective of this study was to determine the percentage of samples remaining intact for each product at various time points. A 95% confidence interval was calculated for each product/time point. Lift was calculated only for samples remaining on the skin.

Results
Table 1 describes the tapes tested and the actual percent of samples still adhered to skin at days 7, 14, and 21.

Table 1: Tapes survival at 7, 14 and 21 days.

<table>
<thead>
<tr>
<th>TAPE ID</th>
<th>TAPE NAME</th>
<th>DESCRIPTION</th>
<th>SAMPLES ADHERED AT 7 DAYS</th>
<th>SAMPLES ADHERED AT 14 DAYS</th>
<th>SAMPLES ADHERED AT 21 DAYS</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>1533L</td>
<td>Single coated rayon nonwoven tape - acrylate adhesive</td>
<td>100%</td>
<td>88%</td>
<td>64%</td>
</tr>
<tr>
<td>5</td>
<td>9873H</td>
<td>Single coated polyester nonwoven tape – tackified acrylate adhesive</td>
<td>100%</td>
<td>88.5%</td>
<td>50%</td>
</tr>
<tr>
<td>3</td>
<td>1776</td>
<td>Single coated polyester nonwoven tape - acrylate adhesive</td>
<td>100%</td>
<td>84.6%</td>
<td>46.2%</td>
</tr>
<tr>
<td>4</td>
<td>9834</td>
<td>Single coated polyurethane film tape - acrylate adhesive</td>
<td>96.2%</td>
<td>80.8%</td>
<td>69.2%</td>
</tr>
<tr>
<td>6</td>
<td>9841</td>
<td>Single coated polyurethane film tape - acrylate adhesive</td>
<td>80%</td>
<td>60%</td>
<td>50%</td>
</tr>
</tbody>
</table>

While the previous Table shows a percentage of tapes remaining adhered to skin, that does not tell the full story.

Figure 3: Proportion of samples remaining on the backs of the volunteers at Days 7, 14 and 21 respectively. Error bars represent results that could be expected when repeating the study with similar parameters.
In the survival estimate chart below, Figure 4, one can track the percentage remaining adhered as a function of wear time. Due to the high variability of skin, greater than 80% survival at a given time is considered a good result.

**Figure 4:** Survival Estimate of each tape, illustrating the progression of tapes lost.

![Survival Estimate Chart](image)

Subjects were not able to see their tape samples based on position. Due to the long wear time, some samples failed for reasons not related to a true lifting failure. However, failure may have occurred due to tape(s) catching on clothing especially when placed near the waist or bra strap.

A lift rating of 0 means that there is no noticeable lift anywhere on the tape. A lift rating of ‘1’ equates to a sample lift of 1% up to 25%. A lift rating of ‘2’ =26% to 50%, ‘3’=51% to 75%, ‘4’=76% to 99% and a ‘5’=the sample is completely missing. When understanding lift measurements it is important to keep in mind that a ‘1’ may be barely perceptible with respect to the tape lifting.

Average lift rating reported on samples attached to skin. Lower lift scores are preferable. Skin sites vary so it is imperative to test tape substrates on the actual site in each application.

**Figure 6.** This figure illustrates total lift scores ONLY for intact tapes, tapes that were still attached at those time points. (Exclusive of fall offs.)

![Mean Lift Across Time](image)

The skin was graded following these guidelines:

0=No redness (of the skin)
1=Slight redness, barely perceptible
2=Definite redness
3=Severe redness (well defined) with edema
4=Extreme response with edema (swelling)

**Figure 5:** Skin condition was evaluated at two time intervals, 10 and 21 days. The graph illustrates the mean skin grading scores at Day 10 and Day 21. Lower scores are preferable, skin is scored within three to five minutes of removal.

![Skin Irritation Graph](image)

**Figure 7:** Chart illustrates the average pain response for tapes at Day 10 and 21. The scale is listed in Fig.8.

![Pain Upon Removal Graph](image)
Subjects were asked to rate the pain they experienced when their samples were removed at Day 10 and again on Day 21. Subjective pain was rated on a Visual Acuity Scale with a numeric pain index from 0 to 110mm. The first 10 mm is equal to a tugging sensation with no pain.

**Figure 8: Instructions for use for Visual Acuity Scale:** Subject makes a vertical line on the above scale, which is measured in millimeters from the right edge of the green zone to the right edge of the scale. Anything marked in the green zone is considered a pain score of ‘0’.

Skin tolerated the tapes quite well at 10 and even 21 days, especially with tapes having breathable backings. A breathable backing is one which allows air or oxygen to flow through the material.

Through Day 14, all but tape 9841 had a survival rate greater than 80% and should be considered for longer wear applications. Tapes that demonstrated the longest wear were 9834 and 1533L with a survival rate above 60% at 21 days.

When evaluating an adhesive tape for a project/product, either a medical device or a stick-to-skin product, consider factors discussed in this report such as breathability, lift, skin condition, estimated duration needed to adhere to skin in order to have the most appropriate tape.

3M Medical Materials & Technologies is continuing to evaluate other adhesives and backings to improve longevity of wear time while maintaining skin integrity.

**Discussion and Conclusion**

The performance of these five acrylate tapes was monitored over 21 days. There were no adverse events reported. These tapes were generally considered comfortable to wear by the subjects throughout the entire study.

Wear time was the most important take away from this study. The science of skin describes cell regeneration approximately every 27 days with the stratum corneum, the uppermost layer, turning over approximately every 14 days. The objective of the study was to determine approximate duration these samples would last on the skin. It was not intended to recommend tape use on skin for longer than two weeks. Removal of the interim tapes at 10 days was included in this protocol to observe skin condition mid-point, ensuring no skin breakdown.

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