

Evaluation of Wear Time for Various Tapes on Human Volunteers: 8-day Study

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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 adhesion time of 10 commercialized and two experimental tape constructions on non-compromised skin in healthy volunteers. This paper concentrates on the commercialized products using acrylate adhesives and a synthetic rubber adhesive. The adhesive in all the tapes had been subjected to ISO 10993 testing for body contact of up to 30 days for a surface device on intact skin. All tapes were evaluated using a uniform set of conditions allowing the tapes to be compared to each other and to better understand their properties.

The study was done in St. Paul, Minnesota and the daily temperature range during the study was between 72 to 88 degrees Fahrenheit with above average humidity.

Subjects and Methods

This Institutional Review Board (IRB) approved study was done in controlled conditions on the backs of 22 healthy volunteers. The study was split into two arms, each having 11 subjects and six tapes unique to each arm.

This was a controlled study where subjects were asked to limit shower length, only front showers, no swimming or hot tubs, and to avoid vigorous activities. Subjects were asked to refrain from using moisturizers or other skin contact 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 doing so 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 to skin contact.

The skin was washed and the samples were applied on the back (3 replicates of 6 different tapes on each subject). The subjects were instructed to keep a diary of showers (time and duration) and activities, as well as any event of tape falling off. Subjects maintained regular activities. At Day 8, observations were made to evaluate lift pre removal, and residue and skin irritation post removal. The primary endpoint was the percentage of samples remaining adhered to skin for each product at various time points. Photos were taken at intervals to collect a visual record of skin condition, backing changes, lift and wrinkling of the backing(s).

Statistical Methods

Wear time or time to sample removal was examined using the appropriate survival methods that take censoring and study design into account. The Kaplan-Meier survival curve was created for each sample in the study, but direct comparisons between products was not necessary. The primary objective of this study was to determine the percentage of samples remaining adhered to skin for each product at various time points. A 95% confidence interval was calculated for each product/time point.

Results

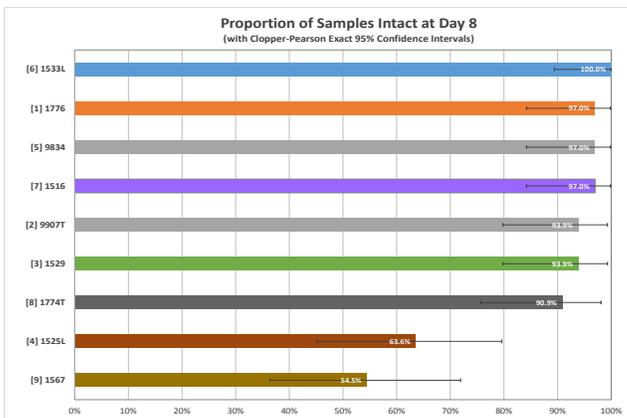
Table 1 describes the tapes tested and the percent of samples still adhered to skin at the end of the study.

Table 1: Tapes placed in rank order by survival.

TAPE ID	TAPE NAME	DESCRIPTION	SAMPLES ADHERED AT 8 DAYS
6	1533L	Single coated rayon nonwoven tape - acrylate adhesive	100.0%
1	1776	Single coated polyester nonwoven tape - acrylate adhesive	97.0%
5	9834	Single coated polyurethane tape - acrylate adhesive	97.0%
7	1516	Single coated polyester film tape - tackified acrylate adhesive	97.0%
2	9907T	Single coated tape elastic nonwoven blend - acrylate adhesive	93.9%
3	1529	Single coated rayon nonwoven tape - acrylate adhesive	93.9%
8	1774T	Single coated tape thin polyolefin foam tape - acrylate adhesive	90.9%
4	1525L	Single coated polyethylene film tape - acrylate adhesive	63.6%
9	1567	Double coated polyester tape - synthetic rubber adhesive	54.5%

Length of wear time may vary on application, thickness, area on body, and age of user

Figure 1: Bar graph with Confidence Intervals (CI), which represent expected results if this study were to be repeated using similar parameters.



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

In the survival charts below, 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 defined operationally as acceptable. Seven of the commercialized tape products met or exceeded the 80% survival criteria at day eight.

Figure 2: Illustrates the progression of tape loss. Each notch represents tape loss.

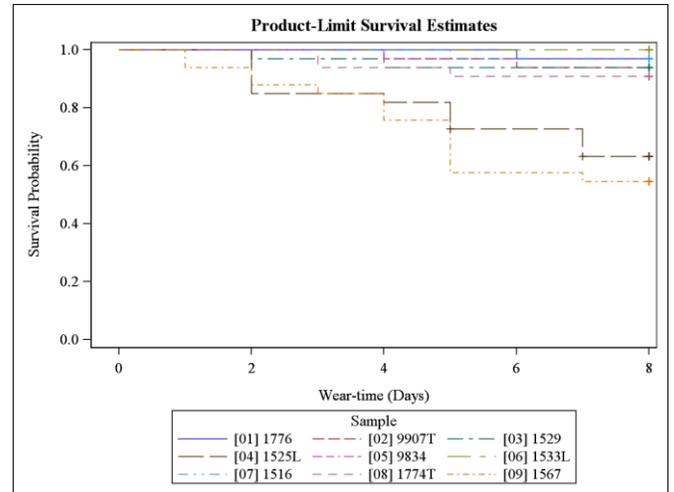


Figure 3: Illustrates the number of samples lost per subject. This alludes to person to person variability when wearing adhesive tapes.

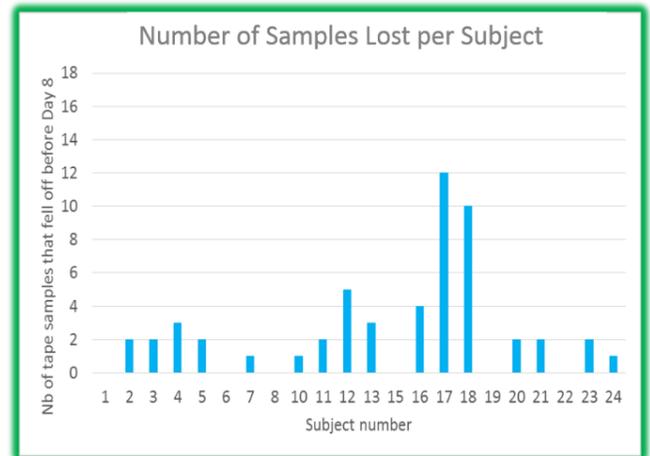
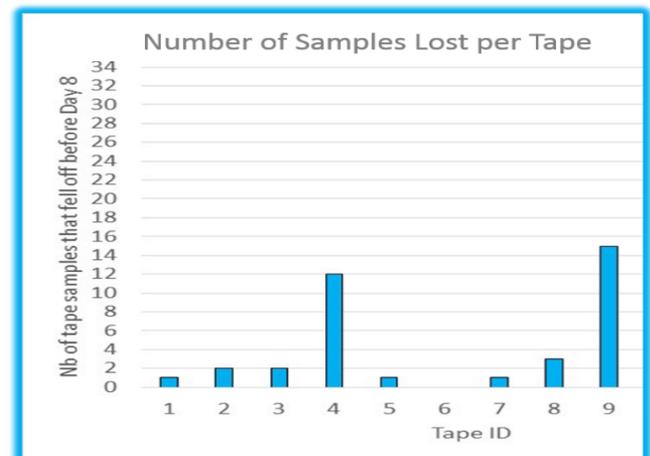


Figure 4 illustrates the total number of each tape that fell off during the study.



While Figure 3 illustrates the range of samples lost per subject, it is important to note that six subjects lost NO tape samples. The results are interpreted to imply that the tapes 1567 [#9] and 1525L [#4]) appeared less suited for long term wear directly on skin, both in terms of duration of adhesion and skin condition. Tape 1516 (#7) performed poorly with respect to skin condition although it had a 97% survival rate at eight days. Overall, most tapes exceeded expectations for length of wear (seven days). One particular tape (1533L) stayed on for eight days on all subjects.

Figure 5: Illustrates sample placement on the backs of subjects.

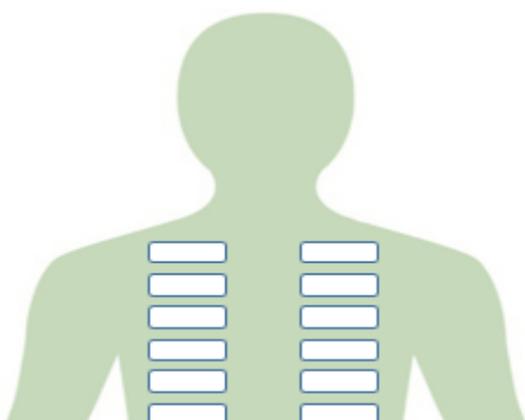


Figure 6



Figure 7



Figures 6 and 7 show placement of tapes on a human subject. The left photo shows an example of the tapes prior to removal on Day 8. The right photo shows skin condition post removal of half the samples after the 8 day wear time. A skin marker was used on the corners of each of the tapes which is readily visible on the tapes.

Figure 8



Figure 8. Photo shows a different subject, with samples removed at Day 8. It is important to examine skin condition after removal of the tape(s). The bottom 3 sites on the left side would be graded as a score of '2'. The lowest site on the right side of the photo demonstrates a score of '1', being barely perceptible. A score of '0' equates to no redness.

Purple marks are from a skin marker used on the corners of each sample which ran along the tape edge on some subjects.

Figure 9

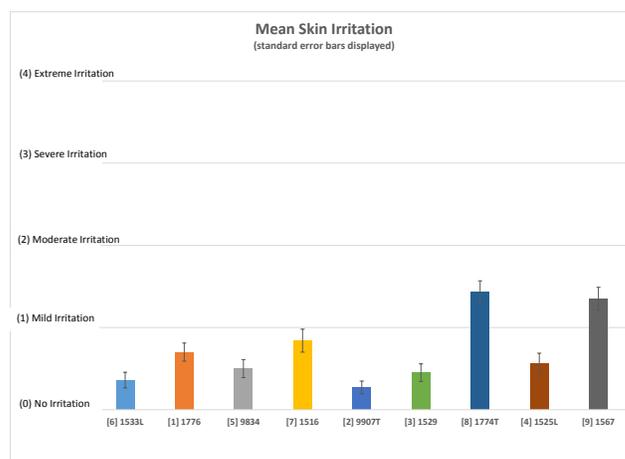


Figure 9. The skin condition was graded at the end of the study following these guidelines:

- 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 10



Figure 10. This image shows a close up photograph of representative tapes illustrating skin oil (sebum) striking through the tape. However this did not appear to affect the performance of the samples. Shown are Tapes 1, 2, and 3.

Discussion and Conclusion

This study examined the performance of several commercialized tapes over wear times beyond those explored in previous studies. Overall, there was minimal lift and there were no adverse events reported. One product, 1533L, a porous rayon nonwoven tape stayed on all subjects for 8 days. Other tapes that performed well were 1776, 9907T, and 9834 which all have porous and/or breathable backings. These four tapes should be considered for applications requiring longer wear. One tape, 1516, had a high survival rate, but due to the occlusive backing, the skin condition demonstrated more irritation than with other tapes. Two other tapes, 1525L and 1567, had higher lift than the others and may not be the best choice for long-term wear directly on skin. 1567 DC High Adhesion Tape can be used for long term attachment for construction.

When choosing a tape, it is important to understand that the backing choice as well as the adhesive plays a significant part in length of wear as well as skin condition. As a result, the particular choice for a given clinical need will reflect a balance between desired wear time, determined primarily by the adhesive and the skin condition on removal with consideration to the combination of the adhesive and the backing.

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