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

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As a device manufacturer, your key consideration when selecting a tape is ensuring proper adhesion to the patient's body. 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. Whether it's affixed for several hours, a day or even a week, your device needs to stay attached to do its job. While adhesion is critical, there are other factors that need to be considered. There are many variables such as ergonomic requirements, skin condition, the patient population or wear time that can affect proper adhesion of your device.

If one looks at the science of human skin, some of the challenges of this substrate become evident. Some of the uncontrolled variables or human factors, include:

- The skin is a dynamic surface, constantly renewing itself.
- Bacteria is present in multiple layers of skin, thus skin cannot be sterilized, only temporarily disinfected.
- Skin grows hair, sweats and produces oil.
- As a person ages, skin becomes thinner, less elastic & easier to damage.

When selecting the right tape for a medical device, some additional factors that may affect adhesion include:

- How long will the device be attached?
- Where on the body will the device be attached?
- What are the device characteristics?
- Who is the targeted end user?

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. Whether synthetic rubber-based adhesives, acrylate adhesives or silicone adhesives, there are features and benefits to each of these medical adhesives to evaluate.

About this study

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 summary provides you with the highlights of the results on the commercially available products and offers insights and information about other parameters to consider when selecting a tape for your device. 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.

SAMPLE BACKINGS AND ADHESIVES PERCENTAGES STILL ADHERED

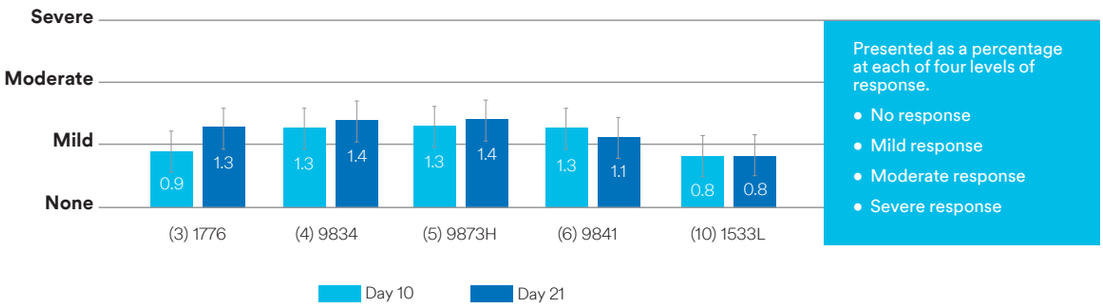
Figure 1: Tapes survival at 7, 14 and 21 days.

TAPE ID	TAPE NAME	DESCRIPTION OF SAMPLE BACKINGS AND ADHESIVES	% SAMPLES ADHERED AT 7 DAYS	% SAMPLES ADHERED AT 14 DAYS	% SAMPLES ADHERED AT 21 DAYS
10	1533L	Single coated rayon nonwoven tape - acrylate adhesive	**100.0%**	**88.0%**	**64.0%**
5	9873H	Single coated polyester nonwoven tape - tackified acrylate adhesive	**100.0%**	**88.5%**	**50.0%**
3	1776	Single coated polyester nonwoven tape - acrylate adhesive	**100.0%**	**84.6%**	**46.2%**
4	9834	Single coated polyurethane film tape - acrylate adhesive	**96.2%**	**80.8%**	**69.2%**
6	9841	Single coated polyurethane film tape - acrylate adhesive	**80.0%**	**60.0%**	**50.0%**

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

INCIDENCE OF SKIN IRRITATION

Figure 2: 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.



Study Notes:

- The study outlined here (Evaluation of Wear Time for Various Tapes on Human Volunteers: 21-day Study) was approved by an Institutional Review Board.
- Healthy participants engaged in normal activities including light exercise and avoided vigorous activities; over the course of the study.
- The study was conducted in May, in the state of Minnesota.
- A different set of study participants might result in a different outcome.

In summary, when choosing a tape construction, 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. The science of skin describes cell regeneration approximately every 28 days with the stratum corneum, the uppermost layer, turning over approximately every 14 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, and estimated duration needed to adhere to skin in order to have the most appropriate tape.

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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70-2011-6757-7