

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

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

As a device manufacturer, your key consideration when selecting a tape is ensuring proper adhesion to the patient's body. 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.

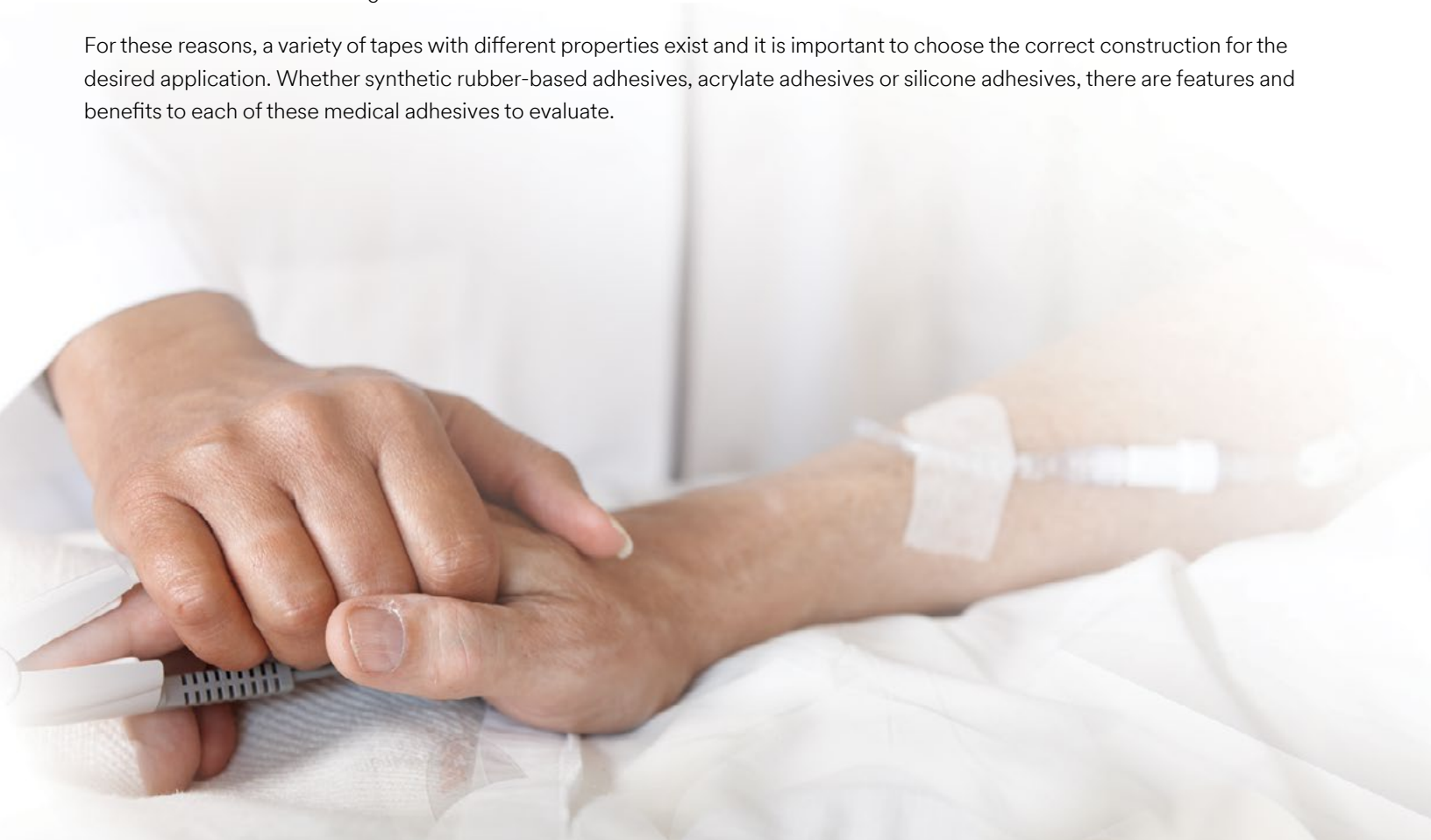
If one looks at the science of human skin, some of the challenges of this substrate become evident. Some of the uncontrolled variables or human factors, include:

- 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 changes and 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?

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 examined the approximate adhesion time of 10 commercialized and 2 experimental tape constructions on non-compromised skin in healthy volunteers. This summary provides you 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.

SAMPLE BACKINGS AND ADHESIVES INTACT AT 8 DAYS PERCENTAGES

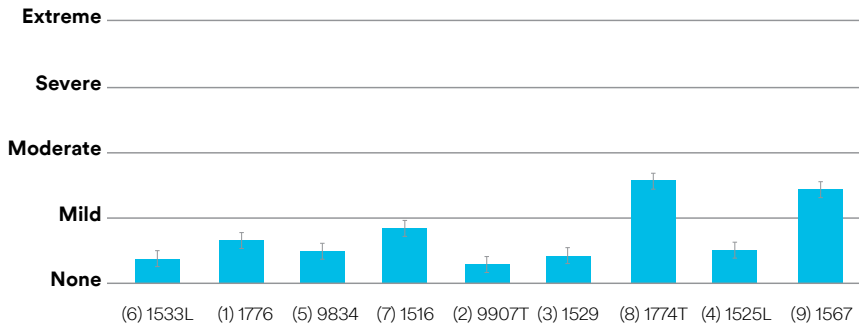
Figure 1: Tapes placed in rank order by survival.

TAPE ID	TAPE NAME	DESCRIPTION OF SAMPLE BACKINGS AND ADHESIVES	% SAMPLES INTACT 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 can vary on application, thickness, area on body, and age of user.

INCIDENCE OF SKIN IRRITATION

Figure 2: Frequency of erythema/edema for each sample. Presented as a percentage at each of four levels of response. Standard error bars displayed.



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. 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.

Study Notes:

- The study outlined here (Evaluation of Wear Time for Various Tapes on Human Volunteers: 8-day Study) was approved by an Institutional Review Board.
- Healthy participants engaged in normal activities and avoided vigorous activities over the course of the study.
- 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.
- A different set of study participants might result in a different outcome.

With over 55 years in the medical adhesive business, no one knows skin better than 3M. We understand the unique challenges of this delicate surface and of the larger design process. Working together, we can help medical device users Wear It Well.

We'll stick with you—by providing the right tape for your device.

Working together, we can help your customers Wear It Well.

Visit 3M.com/MedTech to learn more.



3M Center
St. Paul, MN 55144

Phone 800-584-2787
Web www.3M.com/MedTech

3M is a trademark of 3M.
Please recycle. Printed in U.S.A.
© 3M 2016. All rights reserved.
70-2011-6756-9