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3M Medical Materials & Technologies

Evaluation of Tape Construction on Wear Time for Various Tapes on Human Volunteers: 15-day Study

INTRODUCTION

Wearable technologies in the healthcare market have been available for a very long time, for example, hearing aids, temperature monitors, pulse oximeters and the like. A study in 2014 by MSI and McAfee reported that 70% of people think that wearable technologies will soon send health vitals readings to physicians.[1] The use of adhesives to hold a device on to the skin is not a novel idea. Over time, improvements have been made to adhesives, with adhesives demonstrating a variety of properties to consider. The purpose of this white paper is to provide solutions for choosing adhesives and adhesive systems for creating a well thought through device. Fourteen days are considered 'long term wear' for the wearables market. In order to document 14 days, (good practice procedure) a study needs to extend to 15 days to substantiate that statement. The studies are presented in the order they were conducted.

Consider for a moment alternatives to an adhesive based device. The use of microchips which are implanted in the body for collecting information or transmitting data. Although a viable solution, it is fraught with difficulties. First, it is an invasive procedure. The human body is created to reject foreign bodies; therefore, a chip can be rejected or migrate within the body. Will it be painful to remove? An appropriate scanner for each chip is essential. Would the chip need periodic replacements? Are all the components safe for implantation? Engineers may find a more agreeable solution is a chip *adhered* to the body vs. implanted in the body.

CONSIDERATIONS

Who is the intended audience of a device? Will the device need a gentle shorter wear solution or does it need a longer wear time? It is important to consider multiple factors when determining which adhesive to choose. Will the device or a portion of the device be sterilized? How will it be sterilized and will the adhesive and the device tolerate the chosen sterilization method? Backing selections will impact the performance of a device, along with the type of adhesive use. Breathable backings are aimed at longer more comfortable wear vs an occlusive backing. These are some factors affecting adhesive selection when sticking to skin, but does not include all human variables.

Another consideration in creating a longer wear device is to place an extended border or 'skirt' surrounding the device. The product developer will also want to use a long-term bonding solution holding the device to the backing of a stick-to-skin adhesive tape.

In these studies, a small non-breathable polycarbonate disc was used in place of a real device, referred to as a 'mock' device or sample. This mock device served as a placeholder for a real device, but had no actual function. It was adhered above the skin-friendly adhesive and backing layer. None of the mock devices in these studies were sterilized, but the adhesive tapes used are gamma and/or ETO tolerant.

SUBJECTS AND METHODS

Prior to conducting these studies, three longer term clinical studies were completed (8 day, 21 day, and 15 day). These studies led to narrowing adhesive choices along with investigating other adhesive properties that impact duration. To establish a long-term guideline, two fifteen-day human studies, one with 20 volunteers and one with 16 volunteers were done in house at 3M. These IRB, Institutional Review Board, approved studies included healthy volunteers. The studies are not listed on ClinicalTrials.gov. Volunteers were asked to wear either eight or ten occlusive mock devices on the chest and abdomen. The chest was chosen as a site to simulate the wearing of heart monitors. The abdomen site was chosen to emulate infusion pumps which are normally placed on the abdomen. In each of the studies, the non-sterile samples were randomized.

Device manufactures frequently state the wearers of their devices lead 'active' lives. Therefore, for each of these studies, the participants were asked to maintain their normal activity level and in some cases, subjects engaged in extreme exercise such as running twice a day. Monitoring of activity was done with an activity tracker worn on the wrist. The sole activity restriction was no swimming or hot tub usage. They were allowed to shower according to their normal routine. Information collected from the activity trackers was steps per day, average and high heart rate per day and intensity minutes per week. This collection of activity data allowed us to monitor excessive fall off vs very high activity. Subjects were asked to refrain from using antihistamines which could mask skin changes throughout the study.

The inert 'mock' devices which were used in each of the studies consisted of small polycarbonate plates or discs that were 3 mm x 30 mm x 46 mm with an individual weight of 4 grams. The purpose of using these discs was to simulate occlusive devices and to add slight weight (shear) to the underlying tape. Over the course of each of these studies, the condition of the mock devices was monitored daily by the volunteer or the study coordinator. The actual time of removal or fall off of the device was recorded. No adverse events occurred in these studies.

Lift was observed periodically by the study coordinator. It was collected without disturbing the sample. Skin condition and residue remaining on the skin was noted post sample removal at day fifteen.

Generally speaking, the multiple samples were well tolerated by all participants. In order to reduce protocol deviations subjects were required to send photos of the sites if they were not able to be seen in person. This allowed the study coordinator to verify the samples were or were not attached as the most important outcome of each of the studies was wear time.

Scoring scales, when reported, remained the same for all studies and are as follows:

Lift Scale: 0-100%

Score	Description
0	0=No lift
1	1-25% lift
2	26-50% lift
3	51-75% lift
4	76-100% lift
5	100% lift (fell off)

Skin Condition Scale (Erythema &Edema)

Score	Description of Response
0	No visible response
1	Mild response. Diffused, patchy, not well-defined, just barely perceived erythema. No perceivable edema.
2	Moderate Response. Perceivable erythema is obvious, with diffused redness. Pink or red in color, area well defined. No edema.
3	Severe Response. Obvious erythema. Definite red in color, area well defined. Edema Present.
4	Extreme Response. Bright, fiery red erythema. Edema is present.

Residue Scale

Score	Description
0	No residue
1	1-25% adhesive residue under entire tape sample
2	26-50% adhesive residue under entire tape sample
3	51-75% adhesive residue under entire tape sample
4	76-99% adhesive residue under entire tape sample
5	100% residue

STUDY 1: IMPACT OF EXTENDED ADHESIVE EDGE ON WEAR TIME

16 persons entered and completed this study.

This 15 day trial contained eight unique samples which incorporated 4 acrylate adhesive types with polyurethane film backings.

The primary objective was to confirm or deny the use of an extended border or 'skirt' as a method to promote longer wear vs a non-skirted device. Samples 1-4 all incorporated skirting on the sample. Each of these four samples used acrylic adhesives. Samples 5-8 were non-skirted but otherwise compositionally the same as Samples 1-4. See FIG A.

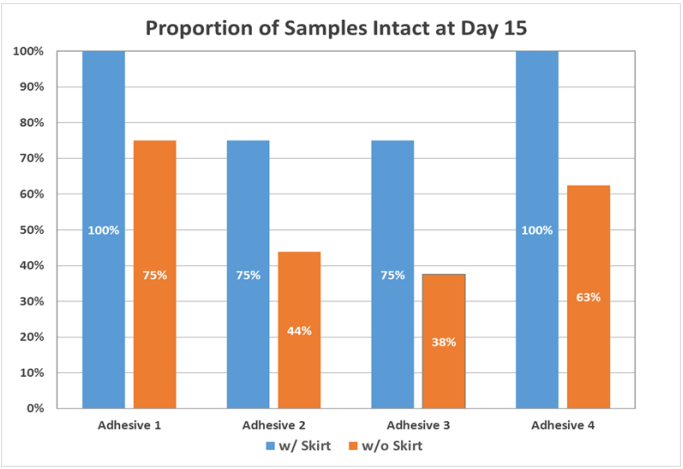
FIG A. IDENTIFIED SAMPLES FOR STUDY 1

#	Sample name **
1	Acrylic Adhesive 1 w/skirt
2	Acrylic Adhesive 2 w/skirt
3	Acrylic Adhesive 3 w/skirt
4	Investigational Adhesive 4 w/skirt
5	Acrylic Adhesive 1 wo/skirt
6	Acrylic Adhesive 2 wo/skirt
7	Acrylic Adhesive 3 wo/skirt
8	Investigational Adhesive 4 wo/skirt

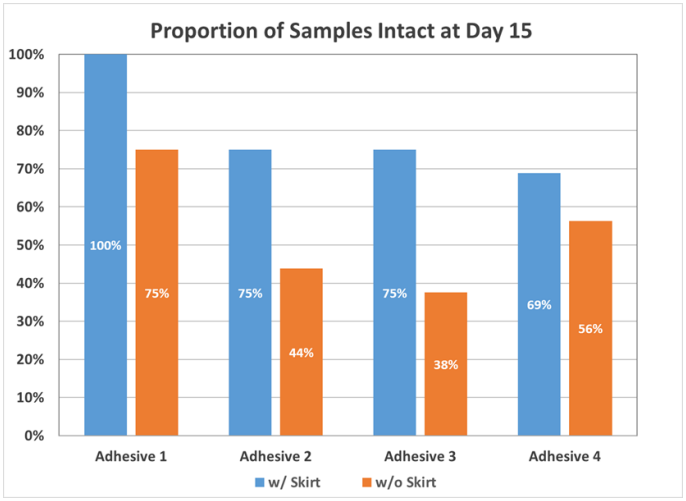
Photos below show ‘mock device’ construction with skirted vs non-skirted sample.

Subjects reported that the reason for fall off often related to catching on clothing. Based on the study design of the mock device, it was likely a fold could catch under the mock device. Seat belts that snagged the device were in close second for lost chest samples. This was noted and sample placement was adjusted as best possible for the following study, to avoid seat belt straps.

As illustrated below, this study points to the benefit of using a skirt around a device. There were two subjects out of sixteen who did not lose any samples for the entire fifteen days.



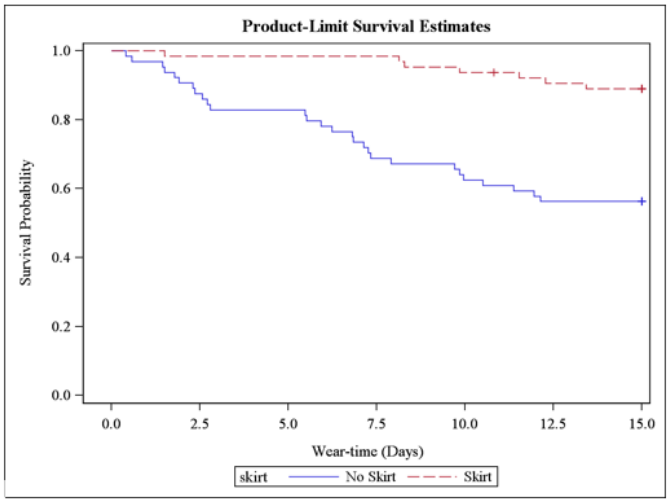
Final study day results demonstrating the percentage of remaining samples still adhered to the skin for each construction.



This graph represents the percentage of samples with the *discs* still attached at Day 15. The interaction of the bonding adhesive layer and the device caused discs to fall off the sample(s) only on Adhesive 4.

On the last day of the study, 35 non-skirted samples were remaining and 56 skirted samples remained. Skirted samples lifted less than non-skirted samples ($p<0.0001$). Day 15, the skirted samples had less overall residue, with the mean (for all samples) at 0.38 vs 0.54 mean for the non skirted samples. Skin condition for the non-skirted version had a mean value of 1.29 for the remaining samples while the skirted version had a mean score of 1.21.

This study demonstrated increased wear time for the skirted samples vs the non-skirted samples ($p<0.0001$).



Survival curve for skirted vs non-skirted samples exclusive of disc fall off.

STUDY 2: EFFECT OF OVERALL TAPE CONSTRUCTION

Extrapolating lessons learned from the prior study, this study was designed by taking the adhesives with the greatest likelihood for long term wear, and combining them with a skirted design. An investigational silicone adhesive was entered into this study to determine if a seven-day wear with this gentle adhesive is feasible. This adhesive is perceived as gentle to remove by the subjects. The other change for this study was to compare two different backings. Both backings used were breathable backings. A breathable backing will have a moisture vapor transmission rate (MVTR) of greater than 250 g/sq.m./24 hrs. This study had 10 samples. Samples #9 and #10 are omitted from this paper as they were investigational samples which are not being considered for commercialization as long wear adhesive options.

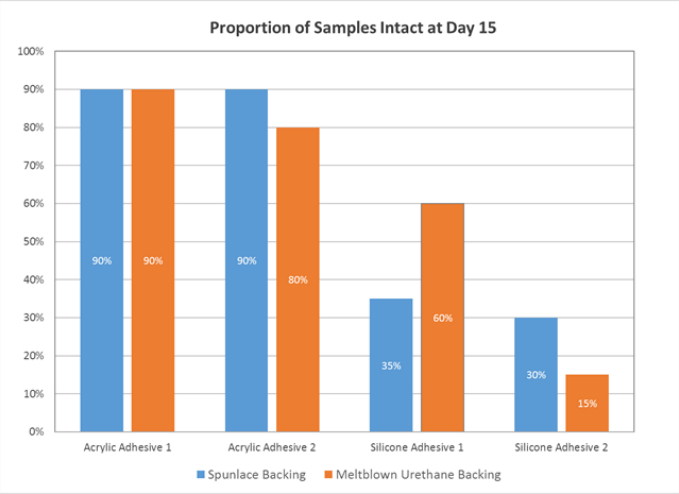
This study included 20 healthy volunteers with each person wearing one sample of each unique mock devices. This paper will share data on eight of the samples. Materials used as shown in FIG B.

FIG B. IDENTIFIED SAMPLES FOR STUDY 2

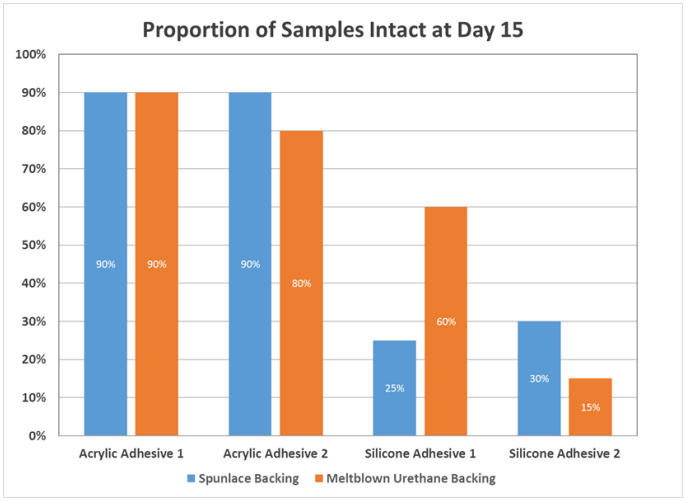
#	Sample name**
1	Acrylic Adhesive 1 on spunlace backing
2	Acrylic Adhesive 1 on meltblown urethane backing
3	Acrylic Adhesive 2 on spunlace backing
4	Acrylic Adhesive 2 on meltblown urethan backing
5	Silicone Adhesive 1 on spunlace backing
6	Silicone Adhesive 1 on meltblown urethane backing
7	Silicone Adhesive 2 on spunlace backing
8	Silicone Adhesive 2 on meltblown urethane backing

Day 15, in nearly all cases, subjects noted how surprised they were to wear these multiple samples with such little discomfort.

Survival at day 15 was 80% or better with both acrylic adhesives using the spunlace and meltblown backings.

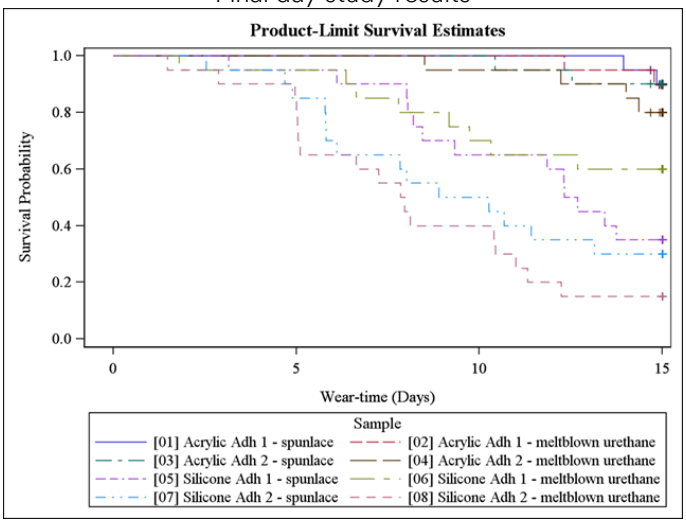


Final study day results demonstrating the percentage of remaining samples still adhered to the skin for each construction.



This graph represents the percentage of samples with the *discs* still attached at Day 15. The interaction of the bonding adhesive layer and the device likely caused discs to fall off Sample 5, Silicone Adhesive 1 on Spunlace.

Final day study results



Survival curve for Samples 1-8 exclusive of disc fall off.

Lift scores on Day 15 averaged under a score of 2 for the samples one through four. Silicone samples five through eight averaged between a score of 2 to 3 on Day 15 although on Day 7, with the exception of Sample 8, the silicone samples had a mean lift score of 2 or under.

Residue left on the skin on day 15 for Samples 1, 2, 3 and 7 remained under a score of two. Sample four exhibited just slightly over a score of 2. There was no apparent residue remaining on Samples 5, 6 and 8. Skin condition on day 15 averaged under a score of 1 apart from Sample 4 which had a skin score of 1.5.

DISCUSSION AND CONCLUSION

We suggest that using an extended tape edge or skirt helps hold the device in such a manner that they held to the skin better than the non-skirted version of the same construction.

Chemistry of the adhesive is important. These studies showed that not all types of tape systems perform equally. A gentle to skin solution uses a silicone adhesive. The duration of wear does not match the acrylate adhesive but up to 8 days is still significant when wearing adhesives on the skin.* The acrylate adhesive shows good promise for up to 14 days, depending on the use. Key to appropriate adhesive selection is to identify the population that prefers gentle removal and repeat use over longer wear times.

The need to explore a range of adhesives and backings cannot be stressed enough when choosing materials.

With 3M medical materials, technologies and healthcare evolution, future innovations point to longer wear adhesives.

*Disclaimer: Based on this investigational study of experimental, non-commercialized product. Further study needed.

[1] *Eichorn, Kim; Ross, Eva (16 September 2014). "U.S. Consumers Predict Unprecedented Connectivity in 2025, but Security and Privacy Concerns Linger" – via ProQuest.*

The adhesive formulations are not necessarily identified consistently throughout the studies.

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