Avery Dennison
Medical
Whitepaper

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Adhesives

Demonstrating 28-Day Wear Time for Medical Wearable Device Applications

Medical wearable devices, such as continuous glucose monitors (CGMs), insulin pumps, drug delivery systems, activity trackers and electrocardiogram monitors, are being continuously optimized by their manufacturers for wear time, performance, size and cost. Adhesive materials that are critical for the interface of medical devices with the human body must therefore keep pace with novel device requirements and feedback from users. For example, the promise of extended wear time can not be realized without the availability of adhesive products designed for multi-week wear.

At Avery Dennison Medical, we set out to engineer a medical adhesive system that offers reliable 28-day wear time. We assembled and evaluated mock devices consisting of a polycarbonate disk bonded to a skin-adhesive tape in a skirt-style construction. We then recruited healthy human informed-consent volunteers to wear a randomized selection of prototypes on the back of their upper arms and recorded the times of application and failure (when the prototype eventually detached). We also noted instances of skin irritation and itchiness throughout the 30-day study. Following that, we assessed reliability by analyzing the time to adhesive failure using Kaplan-Meier non-parametric survival analysis. The prototype evaluated in this study exhibited excellent reliability and was well-tolerated with no irritation during wear. The results emphasize the importance of selecting the right adhesive for the application, and that wear performance is dependent on numerous factors including adhesive chemistry, environment, device design, device location and skin properties.

Introduction

Medical wearable devices or “wearables” are worn on the human body or clothing, which allows for continuous, real-time monitoring of physiological functions for diseases such as cardiovascular disease, diabetes and neurological disorders.[1] Wearables have enjoyed remarkable innovation through advances in batteries, electronics, nanomaterials and computing software—and they continue to evolve. Consider how the size and weight of CGMs have decreased over the past decade, improvements made possible by advances in electronics and sensors. CGMs can now boast of longer duration in use, longer battery life and better data management.[2]

During wearable device development, it is essential to balance the mechanophysiology at the interface of the device and skin, with the diverse fragility of skin. The skin is the body’s largest organ and is made of water, proteins, fats and minerals with features of 10-1000 µm height—all of which impact device adhesion and wear time.[3] Keeping devices attached to skin for weeks at a time requires specialized adhesives.

Such adhesives need to allow sensors to perform as expected and monitor activity without interfering or restricting the user’s movement. Additionally, these devices also must be conformable, breathable and comfortable for the user, as quality-of-life requirements are necessary for device adherence.

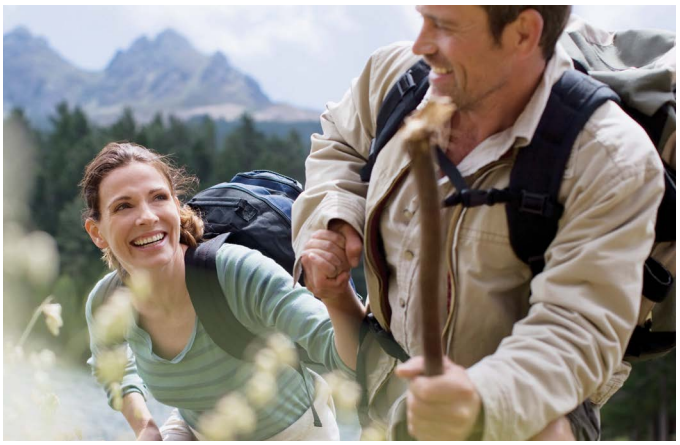
Methods

Materials

This study evaluated wear time for one skin-adhesive tape (MED 5744) and one tie-layer tape (MED 3046) used in combination.

MED 5744 is a single-coated, white polyester (PET) nonwoven with a medical grade acrylic-based adhesive designed for 28-day wear.

MED 3046 is a double-coated, transparent polyurethane (PU) film with a medical grade acrylic-based adhesive on both sides. It is designed to adhere skin carriers to a rigid wearable device.



Methods (continued)

Table 1 and Table 2 show the tested tapes' physical properties. Table 3 shows the products' composition.

Table 1

TYPICAL VALUES FOR PHYSICAL PROPERY TESTING – SKIN-ADHESIVE

Property	Test Method	MED 5744
90 DEGREE PEEL ADHESION ON POLYETHYLENE (PE) [LBF/IN]	TDS-01	2.3
90 DEGREE PEEL ADHESION ON STAINLESS STEEL (SS) [LBF/IN]	TDS-04	> 8.0*
QUICK STICK ADHESION ON STAINLESS STEEL (SS) [LBF/IN]	TDS-05	> 8.0*
90 DEGREE LINER RELEASE [OZ/IN]	TDS-06	2.8
FINAT TACK [LBF/IN]	TDS-07	10.9
STATIC SHEAR [MINUTES]	TDS-12	> 10,000
MOISTURE VAPOR TRANSMISSION RATE (MVTR) [G/M^2 PER 24HR]	TDS-16	64

**Adhesion to stainless steel is higher than the internal strength of the carrier.*

Table 2

TYPICAL VALUES FOR PHYSICAL PROPERY TESTING – TIE-LAYER

Property	Test Method	MED 3046
90 DEGREE PEEL ADHESION ON STAINLESS STEEL (SS) [LBF/IN] – LINER	TDS-04	> 8.0*
90 DEGREE PEEL ADHESION ON STAINLESS STEEL (SS) [LBF/IN] – UNWIND	TDS-04	> 8.0*
90 DEGREE LINER RELEASE [OZ/IN] – LINER	TDS-06	1.0
90 DEGREE LINER RELEASE [OZ/IN] – UNWIND	TDS-06	1.0
ELONGATION – MACHINE DIRECTION [%]	TDS-15	460
ELONGATION – CROSS DIRECTION [%]	TDS-15	429
LOAD AT BREAK – MACHINE DIRECTION [%]	TDS-15	10.6
LOAD AT BREAK – CROSS DIRECTION [LBF/IN]	TDS-15	10.4

**Adhesion to stainless steel is higher than the internal strength of the carrier.*

Methods (continued)

Table 3

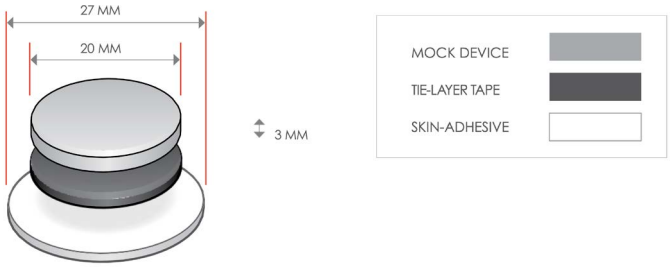
PRODUCT COMPOSITION

	MED 5744 *SKIN-ADHESIVE*	MED 3046 *TIE-LAYER*
LINER	3 MIL WHITE KRAFT PAPER	3 MIL WHITE KRAFT PAPER
ADHESIVE	4 MIL MEDICAL ACRYLIC-BASED *SKIN SIDE*	1.7 MIL MEDICAL ACRYLIC-BASED *LINER / DEVICE SIDE*
CARRIER	13 MIL WHITE POLYESTER (PET) NONWOVEN	1 MIL TRANSPARENT POLYURETHANE (PU) FILM
ADHESIVE	N/A	2 MIL ACRYLIC-BASED *UNWIND / SKIN SIDE (PET NW)*

The skin-adhesive tape MED 5744 and tie-layer tape MED 3046 combination was tested in a wear study trial with a mock polycarbonate device (Figure 1). Each mock device was an island-placed mock device bound to the skin-adhesive tape by using the tie-layer tape. This configuration mirrors the design of commercially available wearable devices, such as CGMs. There were no cover/overlay tapes used in this study.

Figure 1

ILLUSTRATION OF THE PROTOTYPICAL WEARABLE DEVICES EVALUATED IN THIS STUDY



Methods (continued)

Methodology

This study was conducted on healthy human volunteers. Each participant's consent was obtained prior to enrollment in the study. Skin-contacting tape was verified for and passed biocompatibility testing per ISO 10993.

Eligibility criteria

Our researcher screened subjects by pre-determined inclusion and exclusion criteria. The inclusion criteria were: i) adults of at least 18 years of age and in good health, ii) willing and able to follow study directions, iii) willing to restrict swimming to 30 minutes at a time and no deeper than 3 feet underwater, and iv) willing to visit our researcher periodically throughout the study for performance assessments. Exclusion criteria were: i) pregnant and breastfeeding women, ii) acute or chronic skin conditions, iii) known skin allergies to man-made products, and iv) use of oral or parental steroids.

Enrollment and application site preparation

The study was conducted in January in Ohio. On the day of sample application (Day 0), our researcher assessed subjects' skin to ensure compliance with eligibility criteria. The subjects wore six variants of the prototypical wearable device for up to 30 days. Devices were worn on the back of the upper arms (three devices per arm). Prior to device application, the skin of the test sites was cleaned with alcohol wipes (70% isopropanol) and left to dry for at least two minutes. Placement of the prototypes was randomized for unbiased distribution over the test locations across the participant pool.

Assessments

Subjects were asked to wear the prototypes for a period of 30 days. Subjects were allowed to shower and exercise normally; the only restriction was for swimming. Our researcher performed visual assessments of the prototypes every three days using quantitative grading scales, assessing the following characteristics:

- Percentage of the skin-adhesive patch still adhered to the skin (edge lift).
- Appearance of the prototypes, including visual assessments of adhesive residue.
- Subject comfort (itchiness and irritation assessments, pain of removal grading).

The subjects reported the day and time when the prototypes detached from the skin.

Where a prototype had fallen off prior to Day 30, our researcher documented the date, time and conditions under which the prototype detached from the skin. The researcher then calculated the total elapsed wear times for each prototype based on the best available information documenting the removal time. Total wear time was defined as the elapsed time from when the prototype was applied until it became detached from the skin, either intentionally or unintentionally.

Statistical analysis

Our researcher tabulated data and calculated basic summary statistics (mean and 95% confidence intervals). Minitab® statistical software conducted survival analysis. A non-parametric Kaplan-Meier technique was used to generate survival curves from the available data.

Results

Seventeen subjects enrolled in and completed the study. All subjects wore their prototypes until they fell off unintentionally or until the completion of the wear period. None of the subjects intentionally removed their prototypes because of skin irritation or any other reason.

Wear times

The total number of days the prototype was attached to the test site was computed as the elapsed time between the device application and removal (Figure 2). Average wear time was calculated to be 28 days with >80% survival at four weeks.

Adhesion levels

The prototype displayed excellent multi-week wear and reliability. All prototype failures were seen at the skin layer interface, which indicates strong and robust tie-layer performance (100% success rate). Adhesive residue on skin was rated as none to light (invisible but slightly sticky to the touch) after prototype fall-off or removal on Day 30.

Patient comfort

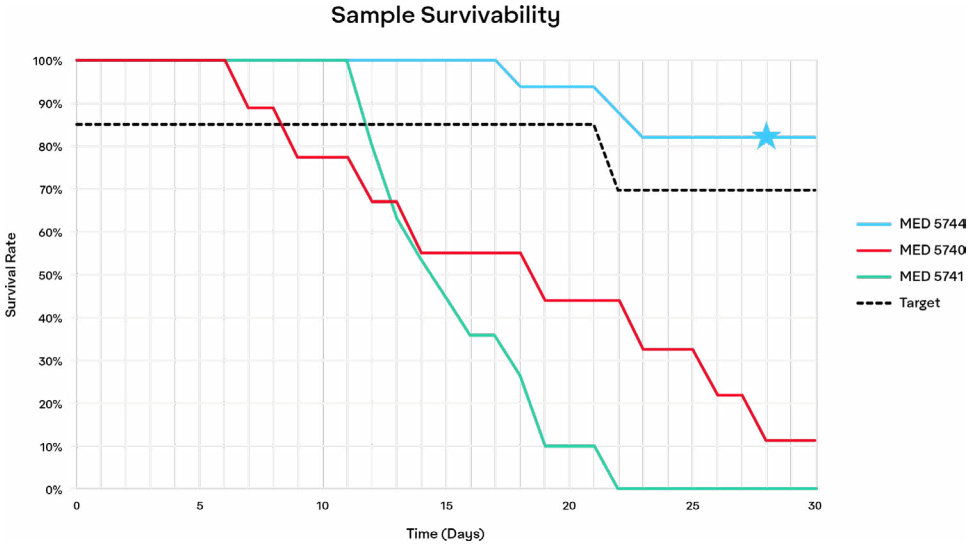
Through 30 days, all participants (100%) reported minimal to no itching. There was no irritation or other discomfort reported during the study's duration. For subjects with a prototype remaining on Day 30, pain of prototype removal was reported as 2.4 (hurts a little bit) on a scale of 10 via the Wong-Baker FACES® Pain Rating Scale.

Prototype location

Prototypes were randomized across six sites on the side of the upper arms, representing typical locations for wearable devices. Wear performance varied across the locations for each prototype, but there were no statistically significant differences in performance.

Figure 2

SURVIVAL CURVES ILLUSTRATING THE PERCENTAGE OF DEVICES THAT REMAINED ADHERED AS A FUNCTION OF THE DURATION OF WEAR TIME AND THE COMPUTED 95% CONFIDENCE INTERVAL



Skin Contact Sample	Survival Rate				Average Wear Time (days)
	7 Day	14 Day	21 Day	30 Day	
MED 5740	89%	56%	22%	6%	16
MED 5741	94%	56%	11%	0%	15.6
MED 5744	100%	100%	94%	82%	28

Note: Our 14-day wear product was also included in the study.

Summary

Recognizing the complexity of skin, a medical device's desired performance attributes, and user requirements are critical in selecting the right adhesive system. The proper balance of adhesion, cohesion, tack and breathability is important because a need exists for secure attachment with easy removal. Inappropriate selections could lead to adhesion failure, skin injury and/or device malfunction.

Skin-adhesive product MED 5744 is a single-coated, white PET nonwoven tape with a medical grade acrylic-based adhesive optimized for 28-day wear applications.

Tie-layer product MED 3046 is a double-coated, transparent PU film with a medical grade acrylic-based adhesive on both sides designed to adhere carriers (e.g. PET nonwoven, PU nonwoven and PU film) to a rigid wearable device (e.g. polycarbonate, polyester, polypropylene and blends) for 28-day wear applications.

This white paper summaries the results of MED 5744 and MED 3046 in a simulated wear application to characterize the product wear performance. This product combination, in a prototypical wear application, demonstrated excellent reliability and long-lasting adhesion on skin, with an average wear time of 28 days. Subjects found the prototype to be comfortable, with minimal to no itching, no irritation or other discomfort at any point during the study, low pain of removal on Day 30 and minimal adhesive residue left on skin after prototype fall-off or removal on Day 30.

The study showcases the importance of adhesive system selection for medical wearable devices. MED 5744 and MED 3046 have distinct physical properties (Table 1 and Table 2) when tested in a controlled laboratory setting. Skin, on the other hand, is dynamic and varies from person to person. For these reasons, adhesive product testing via wear studies is an indispensable marker for success in medical wearables applications.

It is imperative to determine the right adhesive system early in a wearable medical device's development process. The adhesive selection is based on the device's size and shape, its intended wear time, location on the body and the skin's condition.

While the results from this study demonstrate that MED 5744 and MED 3046 display excellent 28-day wear, the wear time for these products could extend beyond three weeks based on wear conditions, the user environment and product design.

Conclusion

28-day wear time can be achieved for medical wearables with the right adhesive tape products, such as MED 5744 and MED 3046. These novel medical adhesive materials open the door for the development of innovative wearable devices that adhere to the skin for an extended wear time providing improved functionality for the patients who use them.

References

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Avery Dennison Medical
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US +1 440 534 2600 MON-FRI, 8AM-5PM ET

INTERNATIONAL +32 14 40 48 11

email medical.solutions@averydennison.com

website www.medical.averydennison.com

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