Second Evaluation of the Wear Duration of Acrylic Wearable Device Adhesives on Healthy Human Volunteers

Bobo J, and Morenz J
Scapa Healthcare

Abstract/Executive Summary

July 2016

Healthy Human wear studies were performed using different formulations of acrylic adhesives on substrates (nonwoven polyester, LDPE film, PU film and PU foam) to evaluate the wear durations of the different combinations. Differences in wear durations were seen depending on the identity of the adhesive and the substrate. When comparing adhesives, no variability in wear duration was attributable to the age or gender of the participants, nor on the amount of bathing or sweating.

Introduction

Wearable devices are becoming more prevalent in the consumer environment with devices that monitor activity related information, such as heart rate and caloric burn. At the same time, technical capabilities have allowed the use of wearable devices to make inroads into healthcare, with devices for monitoring (blood glucose levels) and dispensing (insulin, drugs, electrolytes) coming to market. These devices are expected to become more prevalent as they lessen patient time in medical facilities and lower healthcare costs. Although devices have been available that are attached via straps or modified clothing, the need for the devices to have stable direct skin contact and to be unobtrusive has increased the need for devices that require an adhesive for securement to the skin.

Through Scapa Healthcare's work on wearable devices we have seen the need to develop more knowledge of the wear durations of possible adhesive/substrate combinations. This work is performed on simple adhesive/substrate combinations without the backing of a wearable device and thus presents a worst case scenario as far as material peeling off of the skin over time.

Study Design – Materials

The same control adhesive/substrate combination was used throughout all studies. The control was a nonwoven polyester fabric coated with 2mil thick acrylic adhesive. This control is currently used to adhere a commercial insulin pump to the abdomen of patients.

This report covers four different enrollments of study participants; each enrollment is defined by the substrate that the adhesives were coated onto (**Table 1**). The substrates were chosen due to their commonality of use in the medical adhesive market, range of material composition, thickness, and Moisture Vapor Transition Rate (MVTR).

Table 1 – Characteristics of Substrates

Substrate	Thickness	MVTR ($g/m^2/d$)
Nonwoven Polyester	40 gsm (7.5mil)	7,400
Low Density Polyethylene	3 mil	0
Polyurethane Film	1 mil	1,000
Polyurethane Foam	16 mil	1,800

Five different acrylic adhesives were coated onto the substrates for this study. The adhesives are proprietary, they will only be referred to by letter (A-E). The adhesives were chosen due to their previous use in skin contact products. The adhesives are listed below (**Table 2**) with their physical characteristics.

Table 2 – Characteristics of Adhesive

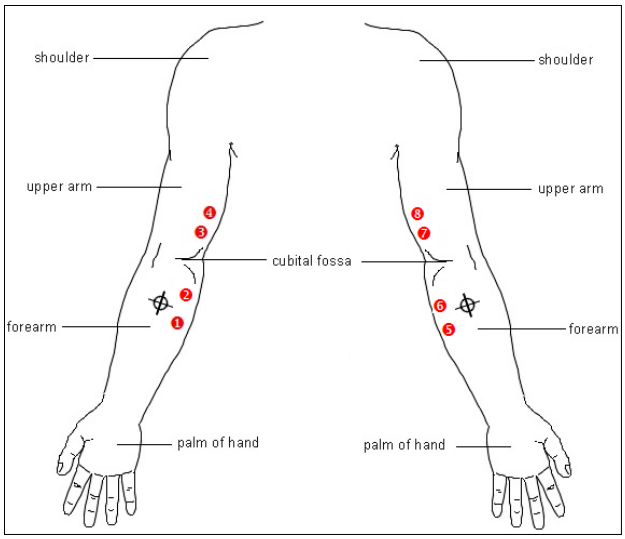
Adhesive	180°Peel from SS (lbf/in) 20 min dwell	Static Shear (hrs)	Info
A	3.6	15 @ $1kg/in^2$	2 mil Coating on 2 mil PET
B	3.5	>300 @ $1kg/in^2$	2 mil Coating on 2 mil PET
C	3.3	128 @ $1kg/in^2$	2 mil Coating on 2 mil PET
D	5.1	13 @ $1kg/in^2$	2 mil Coating on 2 mil PET
E	4.0	24 @ $1kg/in^2$	2 mil Coating on 2 mil PET

Study Design – Plan and Application

Ten participants were enrolled for each substrate phase of the study. Participants were screened to make certain that they did not have any documented allergies to adhesive system components, any active skin disease, raised moles, tattoos, scars, irritated skin or hairs at the test area that could influence the study. Participants were given a brief on the specifics and risks of the study and signed an acknowledgement of the same. Participants were told to continue their daily activities but to avoid scrubbing the samples during bathing and to avoid exposing the samples to creams, moisturizers, and/or ointments.

The sample sites were prepared by cleansing with a pre-moistened alcohol free wipe (Baby Wipe) then with an alcohol wipe and allowed to dry.

Eight round (1 1/8in. : 29mm diameter) samples were placed on the inside arms of each participant, spread out such that 2 samples each were on the right lower, right upper, left lower, and left upper arms. With one control sample and four test adhesive samples, each study enrollment had five different sample constructions. These five sample constructions were distributed across the eight test sites per participant, such that each participant wore either one or two patches of each sample construction. Sample placement across all participants was evenly distributed such that each sample variation was placed at each of the eight test site location on two participants, thus 16 of each sample variation was used in each study enrollment.



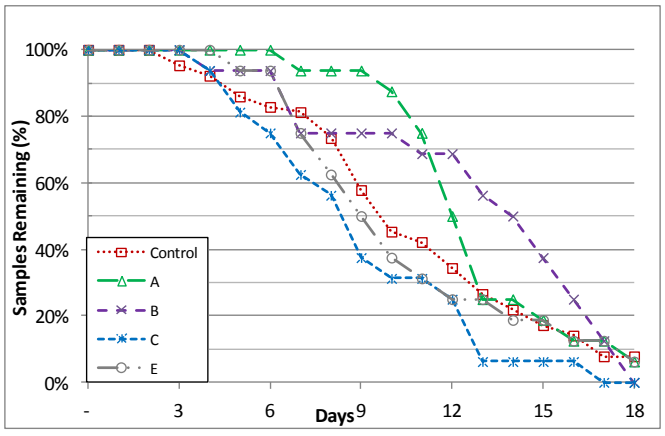
At enrollment, the age, gender and handedness of the participants were documented. Every Monday, Wednesday and Friday out to at least 18 days after affixing of the samples, the participants were questioned as to the loss of samples, along with the number of hours that the samples/sites were: exposed to sweat and bathed or showered. Participants were advised against using creams, moisturizers, and/or ointments on the test areas.

Results

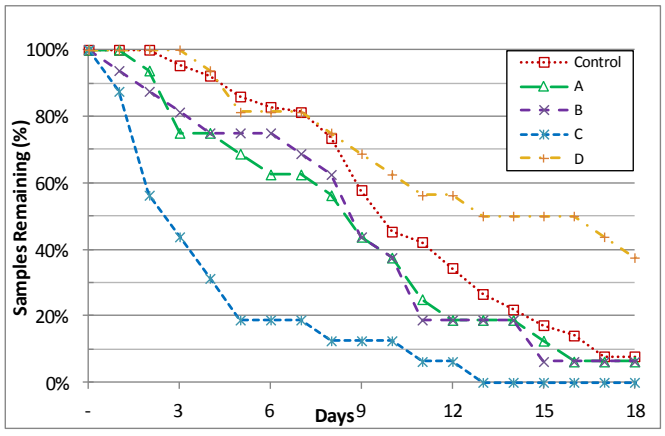
There was no statistically significant difference observed in the effect of sample location, age, gender, hours of sweating or bathing on the wear duration of the samples in any of the studies. Below are graphs of the wear durations of different acrylic adhesives (A through E) on different substrates as percent of samples remaining on participants. After the nonwoven substrate study, Adhesive E, a medium performer, was replaced with adhesive D for the remaining three studies.

As can be seen, differences were observed in the wear duration for samples of the different adhesives on the same substrate (**Graphs 1 through 4**).

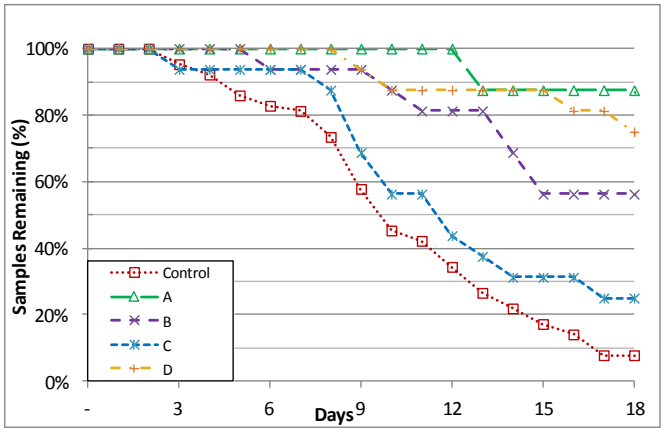
Graph 1 – Nonwoven Substrate



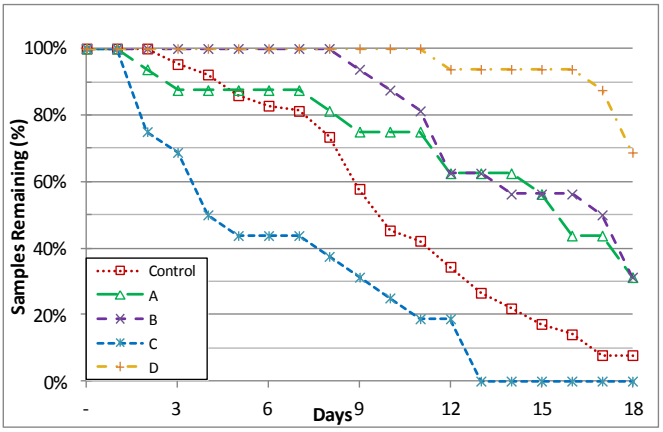
Graph 2 – LDPE Film Substrate



Graph 3 – PU Film Substrate



Graph 4 – PU Foam Substrate



There was a wide range of wear durations observed depending on the acrylic adhesive/substrate combination. There was a tendency for Adhesive C to have the shortest wear duration on all substrates and for Adhesive A, B or D to have the longest adhesions depending on the substrate. The control, a nonwoven polyester, performed in the middle of the nonwovens, in the upper realm versus the LDPE samples and toward the bottom of the PU film and foam samples.

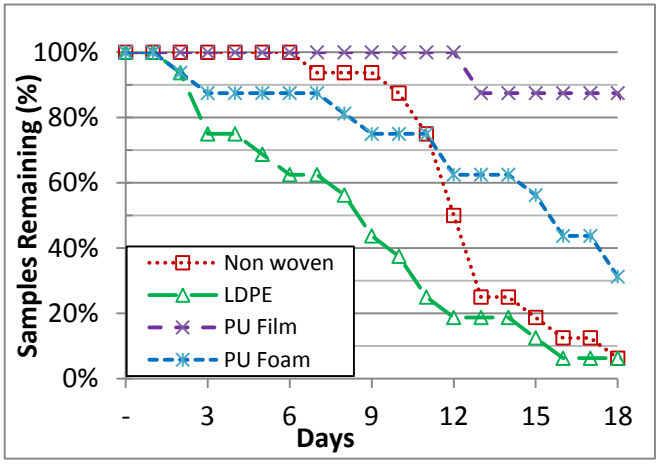
As presented in **Table 3**, the first sample could lose its adhesion (first failure) in as short as 1 day for some of the LDPE substrate samples (**Graph 2**) and as long as 12 or 13 days for some of the PU film and PU foam samples (**Graphs 3 and 4**). There was also a wide range of wear duration for 80% of samples to be lost (a common wear criteria of interest) from <2 days for adhesive C on LDPE to 17 days or greater for some of the PU film and PU foam samples.

Table 3 – Days until First Failure, 80% and 50% of Samples Remaining

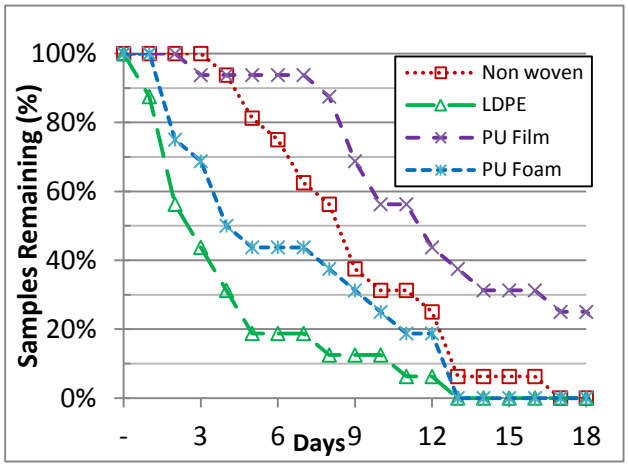
		Nonwoven Substrate				LDPE Substrate		
		1st Failure	80% Remain	50% Remain		1st Failure	80% Remain	50% Remain
Adhesive	A	7	10.5	12	A	2	3.5	8.5
	B	4	6.5	14	B	1	3	8.5
	C	4	5	8.5	C	1	1	2.5
	E	5	6.5	9	D	4	7.5	16
		PU Film Substrate				PU Foam Substrate		
		1st Failure	80% Remain	50% Remain		1st Failure	80% Remain	50% Remain
Adhesive	A	13	>18	>18	A	2	8	14.5
	B	6	13	>18	B	9	11	17
	C	3	8.5	11.5	C	2	2	4
	D	9	17	>18	D	12	17.5	>18

It is also worth viewing a comparison of the same adhesive on the 4 different substrates. **Graphs 5 and 6** are comparisons of the wear duration of Adhesive A (Graph 5) and Adhesive C (Graph 6) on all 4 substrates.

Graph 5 – Adhesive A on All Substrates



Graph 6 – Adhesive C on All Substrates



It can be seen that the longest wear duration is on PU film, with PU Foam or nonwoven polyester being next and LDPE tending to have the shortest wear duration. LDPE is expected to have low wear durations due to the nonexistent MVTR. A lack of moisture permeability can affect the wear duration of a substrate due to the build-up of moisture underneath the substrate during daily activity or exercise. The other substrates have higher MVTRs. Although the nonwoven fabric has the highest MVTR, other substrate attributes are at play here. Both the PU foam and the PU film tend to lie flat on the body, even once the perimeter adhesion begins to give way and pick up dirt. The nonwoven tended to curl up once the perimeter adhesion was lost, leading to greater loss of adhesion.

Conclusion

The Healthy Human wear duration studies carried out by Scapa Healthcare demonstrate the range of wear durations that are experienced with different acrylic adhesives and substrates. This experience is expected to allow for the design of a wearable device with wear durations from less than a day to more than 2 weeks, depending on the adhesive/substrate combinations that are chosen.

FURTHER STUDIES

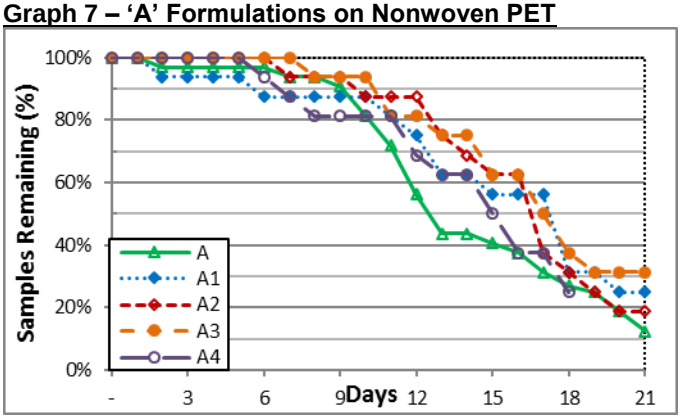
One of the more promising adhesives that was evaluated in the above study was adhesive A, which demonstrated 80% wear durations of 10.5 and >18 days when coated on Non-woven PET and PU film, respectively. Adhesive A is not a straight adhesive but a highly formulated adhesive, which can be readily altered. Further wear studies were conducted, using the same study design as above, using 5 formulations of adhesive A on the same Non-woven PET and PU film to determine whether any longer wear formulations could be identified. Non-woven PET and PU film were chosen due to their performance in the above study.

Results

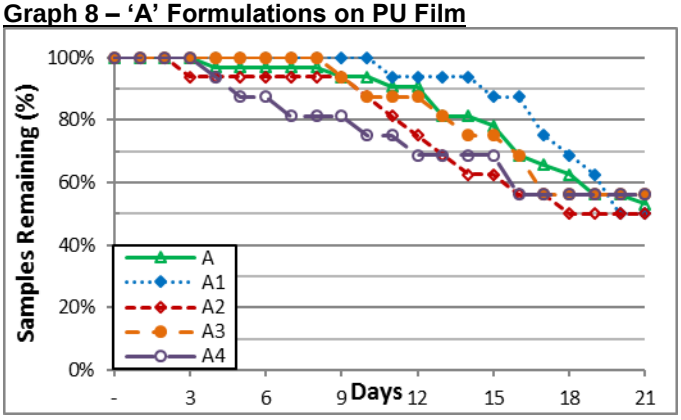
There was no statistically significant difference observed in the effect of sample location, age, gender, hours of sweating or bathing on the wear duration of the samples in these studies. Below are graphs of the wear durations of different acrylic A adhesive formulations (A, and A1 through A4) on Non-woven PET and PU film as percent of samples remaining on participants (**Graphs 7 and 8**).

As can be seen, differences were observed in the wear duration for samples of the different adhesives on the same substrate.

Graph 7 – 'A' Formulations on Nonwoven PET



Graph 8 – 'A' Formulations on PU Film



As presented in **Table 4**, the first sample could lose its adhesion (first failure) in as short as 2 days for some of the Non-woven PET samples (**Graph 7**) and as long as 11 days for one of the PU film samples (**Graph 8**). The range of wear duration for 80% of samples to be lost was relatively tight with a range of 9.5 to 12.5 days for the Nonwoven PET samples and from 9.5 to 16.5 for the PU film samples.

Table 4 – Days until First Failure, 80% and 50% of Samples Remaining for Different 'A' Formulations

		Non-woven PET Substrate				PU Film Substrate		
		1st Failure	80% Remain	50% Remain		1st Failure	80% Remain	50% Remain
Adhesive	A	2	9.5	12.5	A	4	12.5	>21
	A1	2	11.5	17.5	A1	11	16.5	20
	A2	7	12.5	16.5	A2	3	11.5	18
	A3	8	12.5	17	A3	9	13.5	>21
	A4	6	11.5	15	A4	4	9.5	>21

Conclusion

This extension of the Healthy Human wear duration studies focused on identifying formulations of the A adhesive that would have longer wear times than the original A formulation. On the Non-woven PET substrate, all of the alternate A formulations (A1-A4) demonstrated better 80% wear: ranging from 11.5 to 12.5 days versus the 9.5 day wear of the original A formulation. On the PU film substrate, two of the alternate A formulations (A1 and A3) demonstrated better 80% wear: ranging from 13.5 to 16.5 days versus the 12.5 day wear of the original A formulation.

These additional studies carried out by Scapa Healthcare have identified even more candidates for long wear adhesives for wearable devices out to as long as 16.5 days (for 80% wear).

Learn more about Scapa Healthcare

healthcare@scapa.com
scapahealthcare.com

North America
+1 860 688 8000

Europe
+44 (0)161 301 7400

Asia
+852 2439 4330

South America
+55 11 2589 6003