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

Medical Materials & Technologies

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

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Introduction

Medical adhesives can be used in a variety of applications, including securement of wearable sensors, health monitors or other medical devices directly to skin. Depending on the user population, some adhesives need to be gentle for fragile skin or more aggressive to be able to adhere during activities that result in warm, moist conditions. Some tapes need to be more flexible or stretchable to better conform to body contours during movement and 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.

The field of extended-wear medical devices has consistently pushed the meaning of 'extended wear'. Five (5) years ago, it meant 7 days. There are now devices on the market claiming 14-day wear, and recent input from 2 major developers indicate that their next products will have 16-day wear claims (equates to 2 devices/month).

This in-house clinical wear study was a prospective, randomized, open label study on 36 healthy volunteers [19 males and 17 females]. The study was designed to evaluate the extended wear performance of 4 new investigational tapes with mock wearable devices for up to 21 days of wear. All samples were applied to the back of the upper arms on Study Day 0 and worn for up to 21 days to evaluate the survivability at 14 days and wear time up to 21 days. Lift, wear comfort, skin condition, and pain upon removal were also assessed. The investigational acrylic-based adhesives used in these tapes were subjected to a toxicology assessment before the study and were submitted to an outside contract laboratory for ISO 10993 testing for body contact of up to 30 days for a surface device on intact skin.

Subjects and Methods

This 3M Institutional Review Board (IRB) approved study was performed in controlled conditions on the arms of healthy volunteers. This study was not listed on ClinicalTrials.gov. 3M Global Clinical Research and Development Project Team Members employees were excluded.

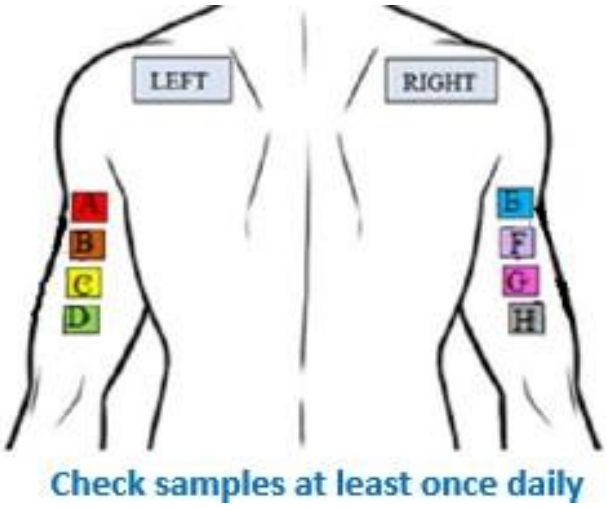
Subjects were asked to refrain from using moisturizers or other skin contacting materials on the test sites during the study and for 24 hours prior to the initial study visit. They were also asked to refrain from taking antihistamines within 48 hours of the study and for the duration of the study as it could mask skin changes. If an excessive amount of hair

existed on the test sites, the area was clipped prior to the initiation of the study to ensure good sample-skin contact. Other than swimming, hot tubs, tub bathing, and submersion of samples there were no activities restricted for the 21 days and all enrolled subjects completed the study.

The skin was assessed and excessive hair was clipped, if necessary, before the areas were washed with a mild soap solution, rinsed and patted dry. Mock devices [overall dimensions were 42 mm x 42 mm with a centered, attached 28 mm x 28 mm hard acrylic plaque] were applied on the back of subjects' upper arms according to a randomized rotational order (2 replicates of 4 different tapes on each subject). The layout of the samples is illustrated in Figure 1. The subjects were instructed to keep a daily diary of activities, as well as any event of tape loss recording date, time and reason if known. Subjects maintained regular activities during the entire 21 days. Skin condition was evaluated before and at the time of sample removal. Pain upon removal was noted at the end point of 21 days. Subjects were asked to rate their pain on a numeric scale with 0 being neutral.

Figure 1.

Illustrates sample placement on the arm.



Statistical Methods

Primary endpoint

The survivability at Day 14 was analyzed by summarizing the proportion of samples still adhered at Day 14.

Secondary endpoints

- Wear time up to 21 days was examined by checking the survival curve for all four samples. Clustered data from the same subject was assessed with the Cox proportional hazard model
- Proportion of samples still adhered on each study day after Day 14 was summarized by running frequency tables.
- Lift, itching, and wear comfort assessed at 7, 14, and 21 days of wear were analyzed by summarizing the frequency of each variable. Lift was also analyzed using a Mixed model repeated measure.
- Erythema, edema, skin stripping, mechanical irritation/blistering, residue (edge and overall), maceration, and pain upon removal after 21 days of wear / EOS was summarized by running frequency tables

Results

Table 1 describes the tapes tested and the actual percent of samples still adhered to skin at Days 14 and 21.

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

Tape ID	Tape Name	Description	% Samples adhered at 14 days	%Samples adhered at 21 days
1	MSX-7401X/ 4578 [blue]	Single coated polyester nonwoven tape – exp XW acrylic adhesive 1	94.4	84.7
2	MSX-7402A/ 4576 [red]	SC polyester nonwoven tape – exp XW acrylic adh. 2	95.8	95.8
3	Experimental 3	SC polyester nonwoven tape – exp XW acrylic adh. 3	90.3	86.1
4	Control [brown]	SC polyester nonwoven tape – commercialized XW acrylic adhesive	68.1	41.7

While the previous Table shows a percentage of tapes remaining adhered to skin, that does not tell the full story. In the Survival Estimate chart below, Figure 2, one can track the percentage remaining adhered as a function of wear time. Due to the high variability of skin, greater than 90% survival at a given time is considered a good result.

Figure 2.

Survival Curve of each tape, illustrating the progression of tapes lost.

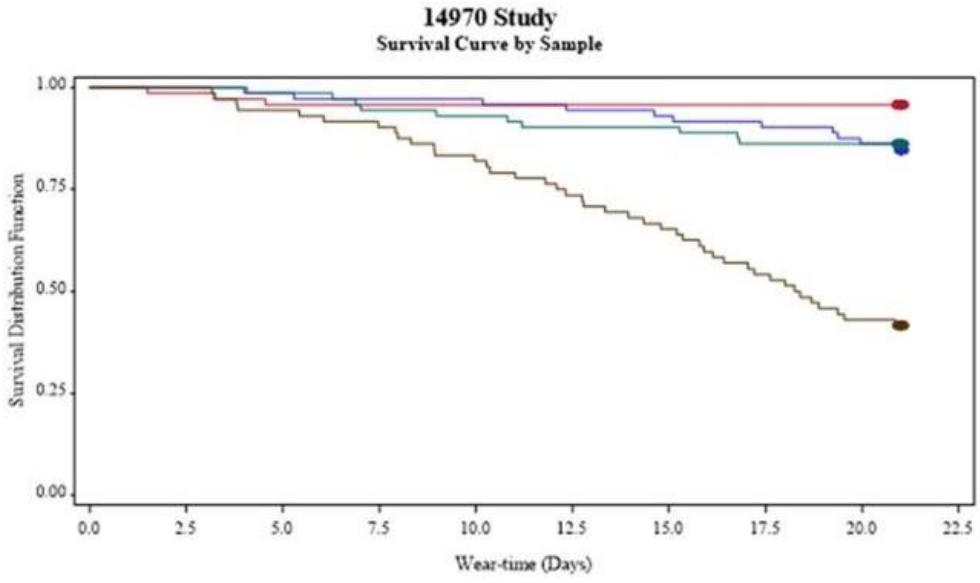
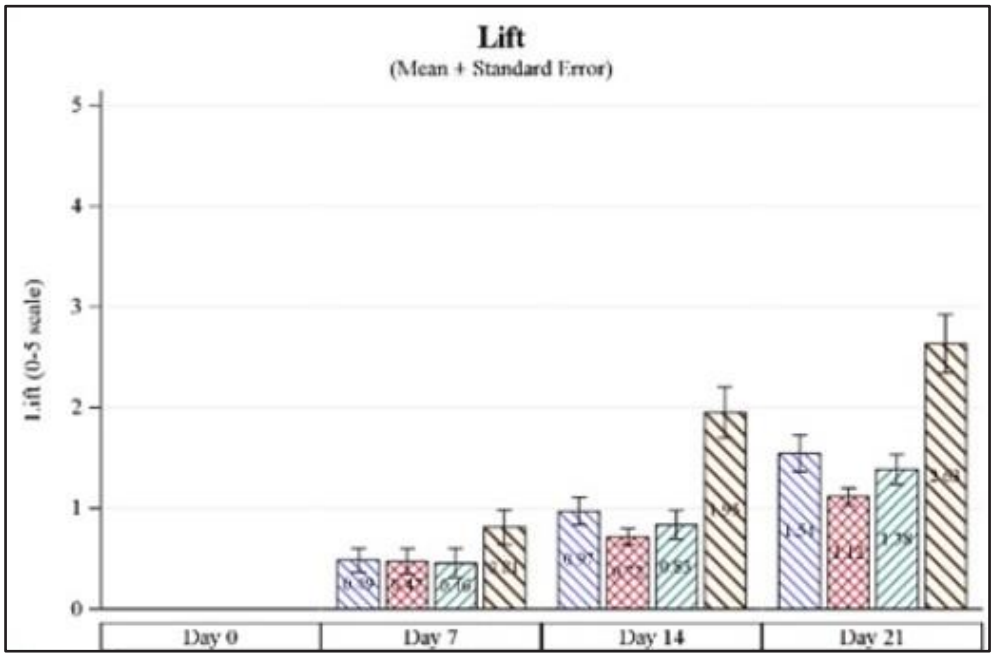


Figure 3.

This figure illustrates total lift scores ONLY for intact tapes, tapes that were still attached at those time points. (Exclusive of fall offs.)
No data collected at Day 0.



Average lift rating is evaluated, scored and reported on samples still attached to skin. Lower lift scores are preferable. Skin sites vary so it is imperative to test tape substrates on the actual site in each application.

A lift rating of 0 means that there is no noticeable lift anywhere on the tape. A lift rating of '1' equates to a sample lift of 1% up to 25%. A lift rating of '2' =26% to 50%, '3'=51% to 75%, '4'=76% to 99% and a '5'=the sample is completely missing. When understanding lift measurement, it is important to keep in mind that a score of "1" may be barely perceptible with respect to the tape lifting.

Figure 4.

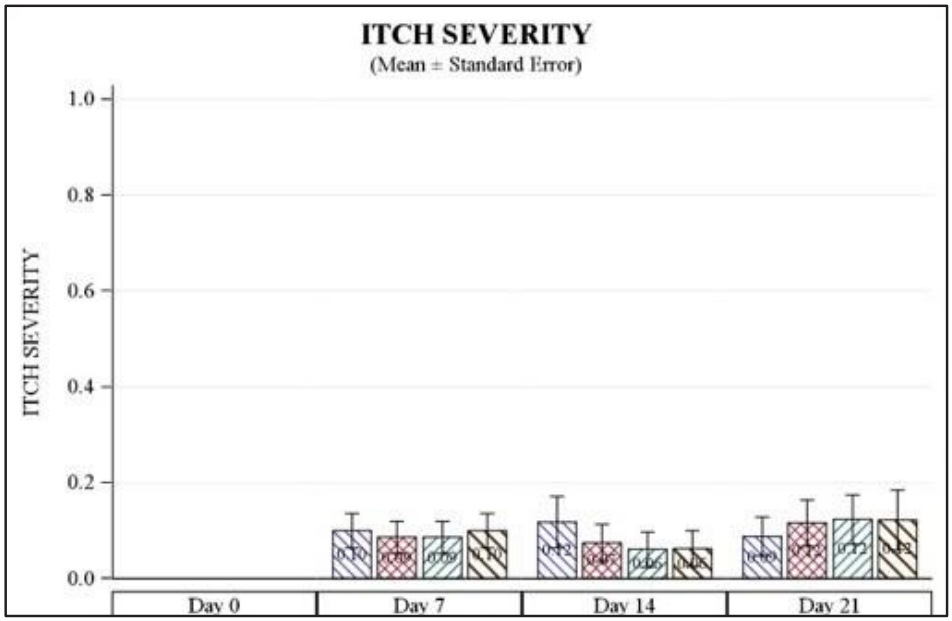
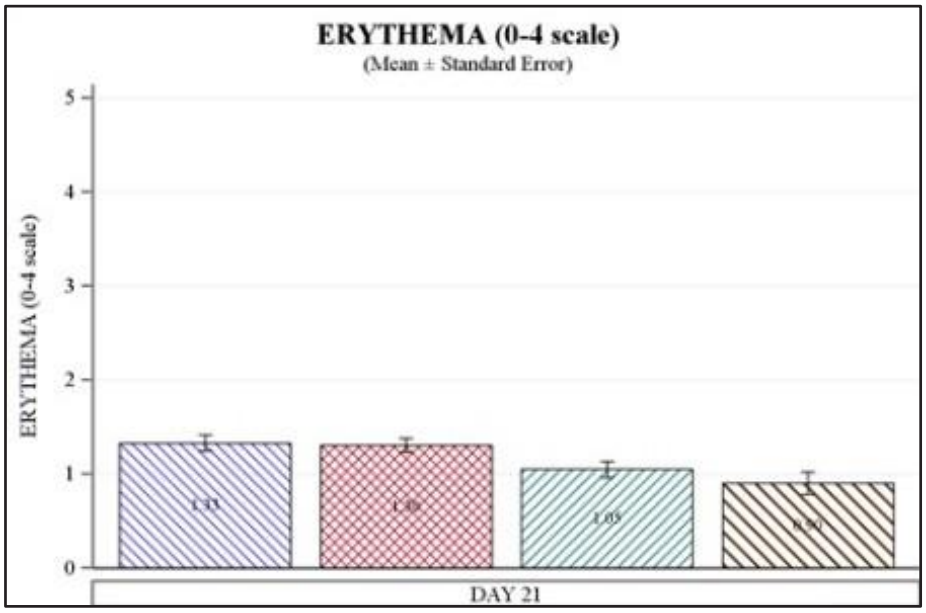


Table 2: Summary of Itch Frequency at 7, 14 and 21 days.

Sample		Summary of Itch Frequency					
		N	Mean	Std	Median	Min	Max
[1] MSX-7401X/4578	Day 7	70	0.13	0.414	0.0	0.0	2.0
	Day 14	68	0.15	0.526	0.0	0.0	2.0
	Day 21	68	0.09	0.334	0.0	0.0	2.0
[2] MSX-7402A/ 4576	Day 7	70	0.11	0.401	0.0	0.0	2.0
	Day 14	67	0.12	0.477	0.0	0.0	2.0
	Day 21	69	0.13	0.451	0.0	0.0	2.0
[3] Experimental 3	Day 7	70	0.11	0.401	0.0	0.0	2.0
	Day 14	66	0.09	0.420	0.0	0.0	2.0
	Day 21	65	0.12	0.415	0.0	0.0	2.0
[4] Control	Day 7	70	0.11	0.401	0.0	0.0	2.0
	Day 14	64	0.09	0.426	0.0	0.0	2.0
	Day 21	49	0.12	0.439	0.0	0.0	2.0

Skin condition was evaluated at 21 days. The graph [Figure 5] illustrates the mean skin grading scores. Lower scores are preferable, skin is scored within three to five minutes of removal.

Figure 5.



The skin was graded immediately after removal following these guidelines:

0=No redness (of the skin)

1=Slight redness, barely perceptible

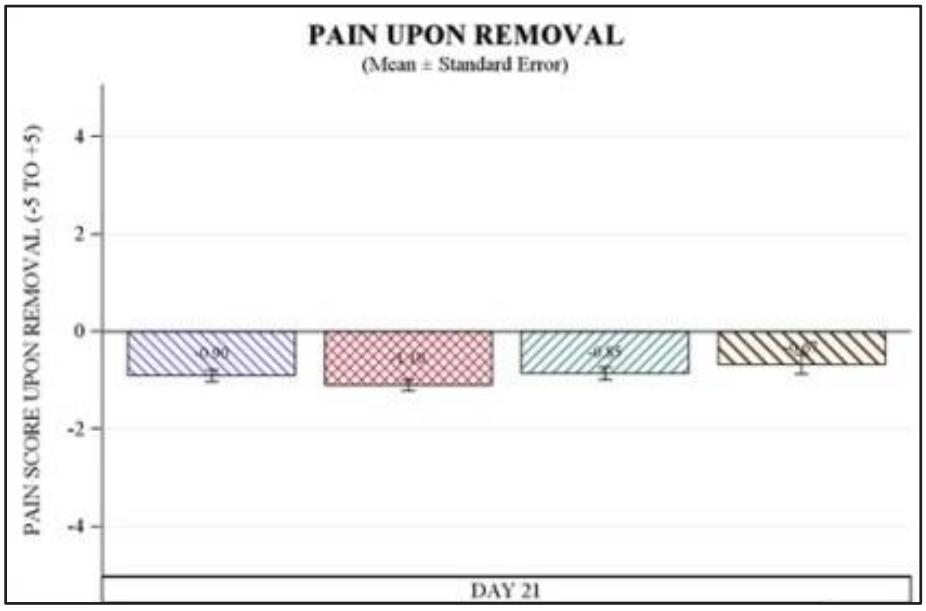
2=Definite redness

3=Severe redness (well defined) with edema

4=Extreme response with edema (swelling)

Figure 6.

Chart illustrates the average pain response for tapes at Day 21.



Subjects were asked to rate the pain they experienced when their samples were removed on Day 21. Subjective pain was rated on a scale with a numeric pain index. During the removal of each sample, subjects were asked to rate their experience with a whole number with negative numbers describing a "painful" experience, zero as a neutral [neither painful nor pleasant] and positive numbers were used for "pleasant" events.

Discussion and Conclusion

The performance of these acrylic-based tapes was monitored over 21 days. There were two mild adverse events reported that resolved themselves the same day as onset. These tapes were generally considered comfortable to wear by the subjects throughout the entire study.

The primary objective of this study was to evaluate the extended wear performance (up to 21 days) of 4 new investigational acrylate adhesive tapes when worn with a mock wearable device. The mock wearable device was included to represent the intended use scenario and add additional shear stress to the tape samples. Wear time was based on adherence of the tape (with or without the plastic disc) to the skin.

When evaluating an adhesive tape component for a project/product, either a medical/retail device or a stick-to-skin product, consider factors discussed in this report such as breathability, lift, skin condition, estimated duration needed to adhere to skin in order to have the most appropriate tape.

The primary endpoint was the survivability at Day 14 (the proportion of samples still adhered). Samples 1, 2, and 3 all met the minimum 14-day survivability requirement, and maintained greater than 90% survivability through 15, 19, and 21 days of wear, respectively. Sample 4 had a survivability of about 75% at Day 14 and did not meet the minimum survivability criteria during this study. Most subjects reported doing vigorous activity between study visits. These activities included housework/cleaning, yard work, sports [including one full marathon], packing/moving, golf, weight training, etc.

Only summary statistics were performed on erythema, edema, skin stripping, mechanical irritation/blistering, residue (edge and overall), maceration, and pain upon removal after 21 days of wear / EOS. Mean erythema scores were <1.4 for all 4 samples. No edema was observed after removal of any sample. The majority of samples (>98%) had no skin stripping, mechanical irritation, or blistering observed at the time of sample removal on Day 21. Maceration after 21 days of wear was observed in <3% of samples.

The majority of subjects experiencing no itching or rare, mild itching. All subjects rated the samples to be either comfortable (11.2%) or very comfortable (88.8%) to wear throughout the 21-day wear interval.

3M Medical Materials & Technologies is continuing to evaluate other adhesives and backings to improve longevity of wear time while maintaining skin integrity.

[i] Dexcom, *G5 mobile Continuous glucose monitoring system Advisory Committee, briefing materials.* 2016.

[ii] Abbott, *FreeStyle Libre 14-day Flash glucose monitoring system Quick Reference Guide.* www.Manualslib.com, 2018.

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