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# Evaluation of Wear Time for Various Extended Wear Adhesive Tapes on Human Volunteers: 28-day Study

Medical Materials & Technologies

# Evaluation of Wear Time for Various Extended Wear Adhesive Tapes on Human Volunteers: 28-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[i].

There are now devices on the market claiming 14−day wear[ii], 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, open label, rotational block design study on 36 healthy volunteers [15 males and 21 females]. The study was designed to evaluate 4 investigational acrylate adhesive tapes, heat−laminated with different backings, all made with the Mercury 1.1 adhesive, including 1 sample from a previous clinical study (EM−05−014970) as an investigational control. All samples were applied to the back of the upper arms on Study Day 0 and worn for up to 28 days to evaluate the survivability at 28 days and wear time curves across the 28 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.

Other than swimming, hot tubs, tub bathing, and submersion of samples, there

were no activities restricted for the 28 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.

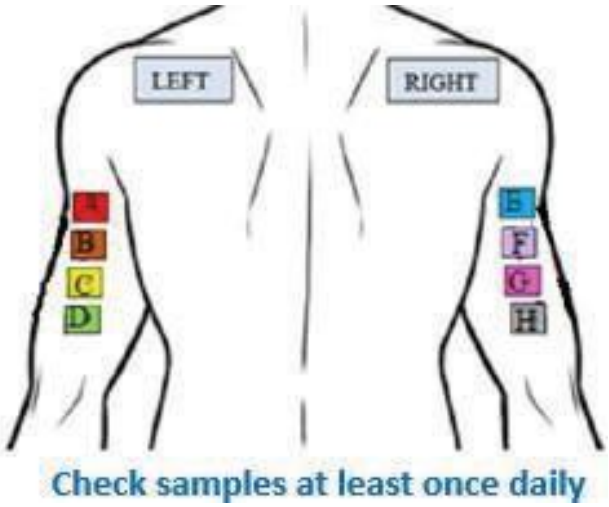
Mock devices [overall dimensions were 42 mm x 42 mm tape with a centered, attached 28 mm x 28 mm hard acrylic plaque] were applied on the back of subjects' upper arms according to a randomized rotational order (2

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. Other than restricting submersion of samples, Subjects maintained regular activities during the entire 28 days.

Skin condition was evaluated before and at the time of sample removal. Pain upon removal was noted at the end point of 28 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 28 was analyzed by summarizing the proportion of samples still adhered at Day 28.

### Secondary endpoints

- Wear time curves for the 28 days were examined by checking the survival curve for all four samples. Clustered data from the same subject was assessed with the Cox proportional hazard model. A Kaplan−Meier curve was generated to display survival across time.
- Sample lift, lift of the skirt, mock device lift (i.e., the acrylic plaque lifting from the tape), itching, and wear comfort assessed at 7, 14, 21 and 28 days of wear were analyzed with summary and frequency tables for each variable and by a mixed model ANOVA.

- Erythema, edema, skin stripping, mechanical irritation/blistering, residue (edge and overall), maceration, and pain upon removal after 28 days of wear were analyzed with summary and frequency tables for each variable and by a mixed model ANOVA.

## Results

Table 1 describes the tapes tested and the actual percent of samples still adhered to skin at Day 28. In addition, the number of days where 90% or greater samples were adhered is recorded for each tape.

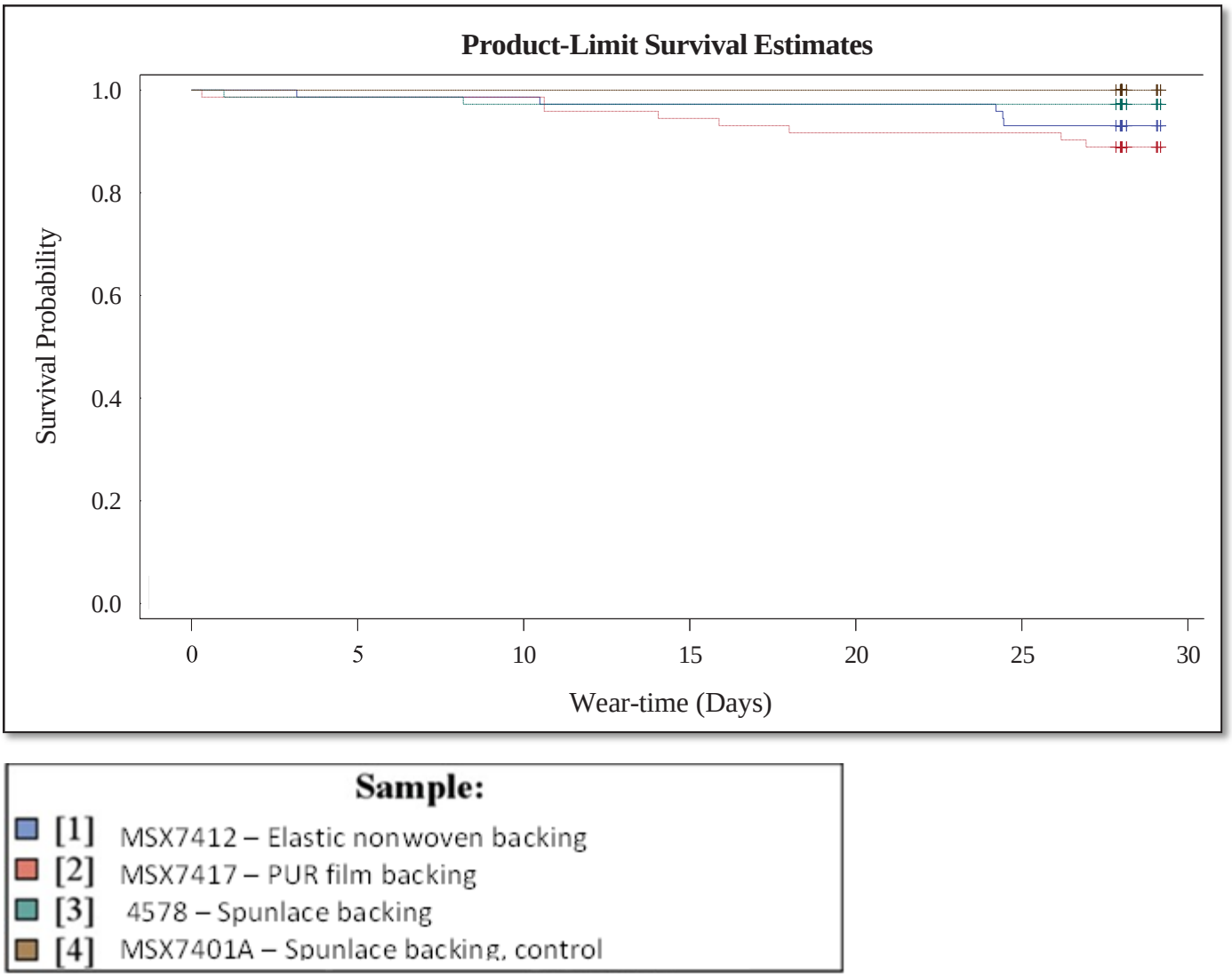
### Table 1: Tape survival at 28 days and last day of 90% adherence

| Tape ID | Tape Name | Description | % Samples adhered at 28 days | Last day that 90% of samples adhered |
|---|---|---|---|---|
| 1 | MSX-7412 | Elastic nonwoven backing, unsterilized | 93.1 | 28 |
| 2 | MSX-7417 | PUR film backing, unsterilized | 88.9 | 26 |
| 3 | 4578 | Spunlace backing, unsterilized | 97.2 | 28 |
| 4 | MSX-7401A | Spunlace backing, unsterilized Control | 100.0 | 28 |

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.



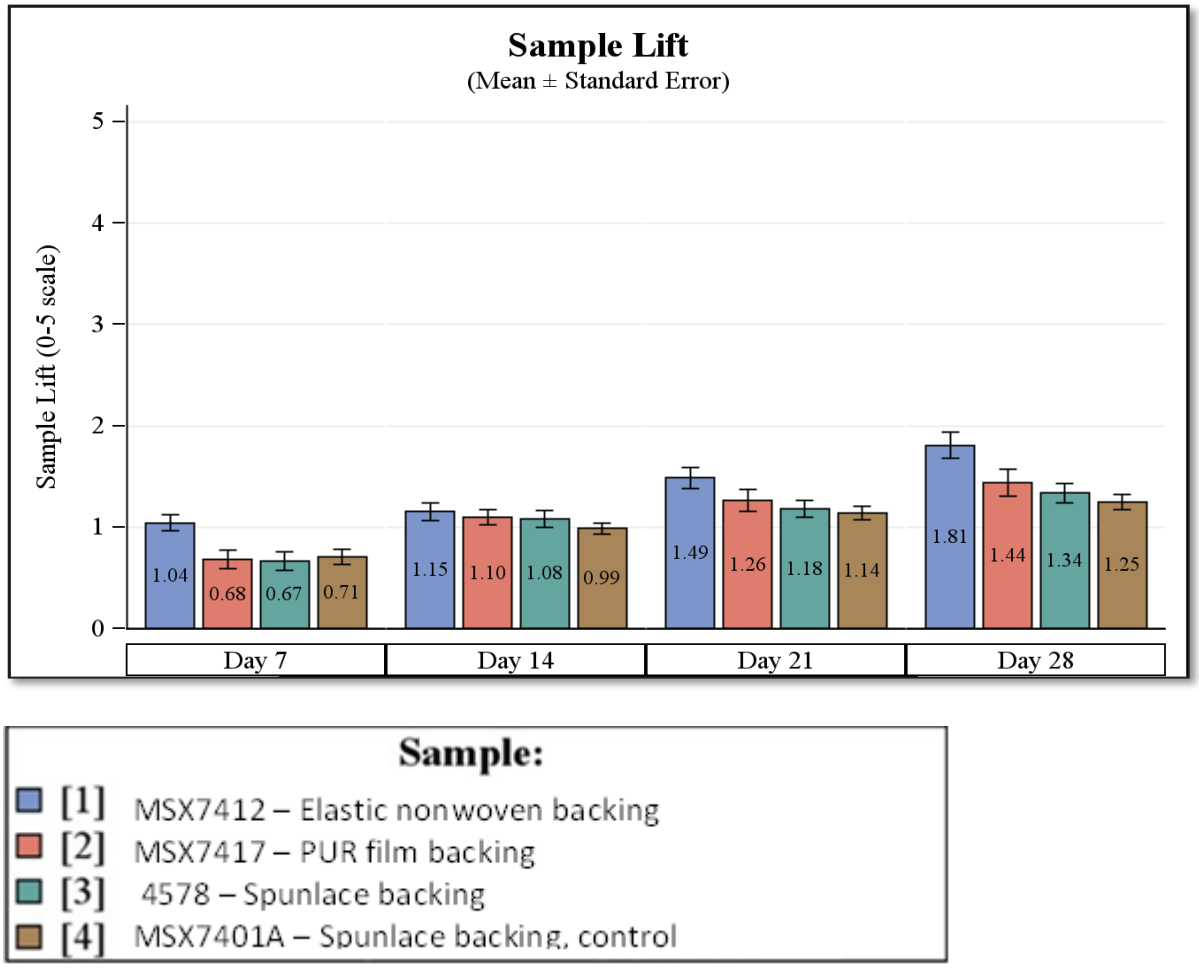
Average sample lift rating is evaluated, scored, and reported at each study visit. Lower lift scores are preferable. Skin sites vary so it is imperative to test tape substrates on the actual site in each application.

A lift rating of 0 means that there is no noticeable lift anywhere on the tape. A lift rating of '1' equates to a lift of 1% up to 25% of the area being assessed. A lift rating of '2' =26% to 50%, '3'=51% to 75%, '4'=76% to 99% and a '5'=100% lift (for sample lift and skirt lift). For the mock device (i.e., the acrylic plaque), a lift rating of '1' was given if the 'mock device partially lifted from the tape', and a rating of '2' was given if the 'mock device fell off the tape'. When understanding lift measurement, it is important to keep in mind that a score of "1" is considered minor with respect to the tape lifting.

By Day 28, mean *sample lift* scores were between 1 (>0%−25%) and 2 (26%−50%) for the four samples (mean range, 1.25−1.81). Sample [1] MSX−7412–had statistically more sample lift than all three of the other test samples on Days 7, 21, and 28 (see figure 3).

***Figure 9.***

This table illustrates sample lift scores. Fall offs were scored “5” (100% lift).

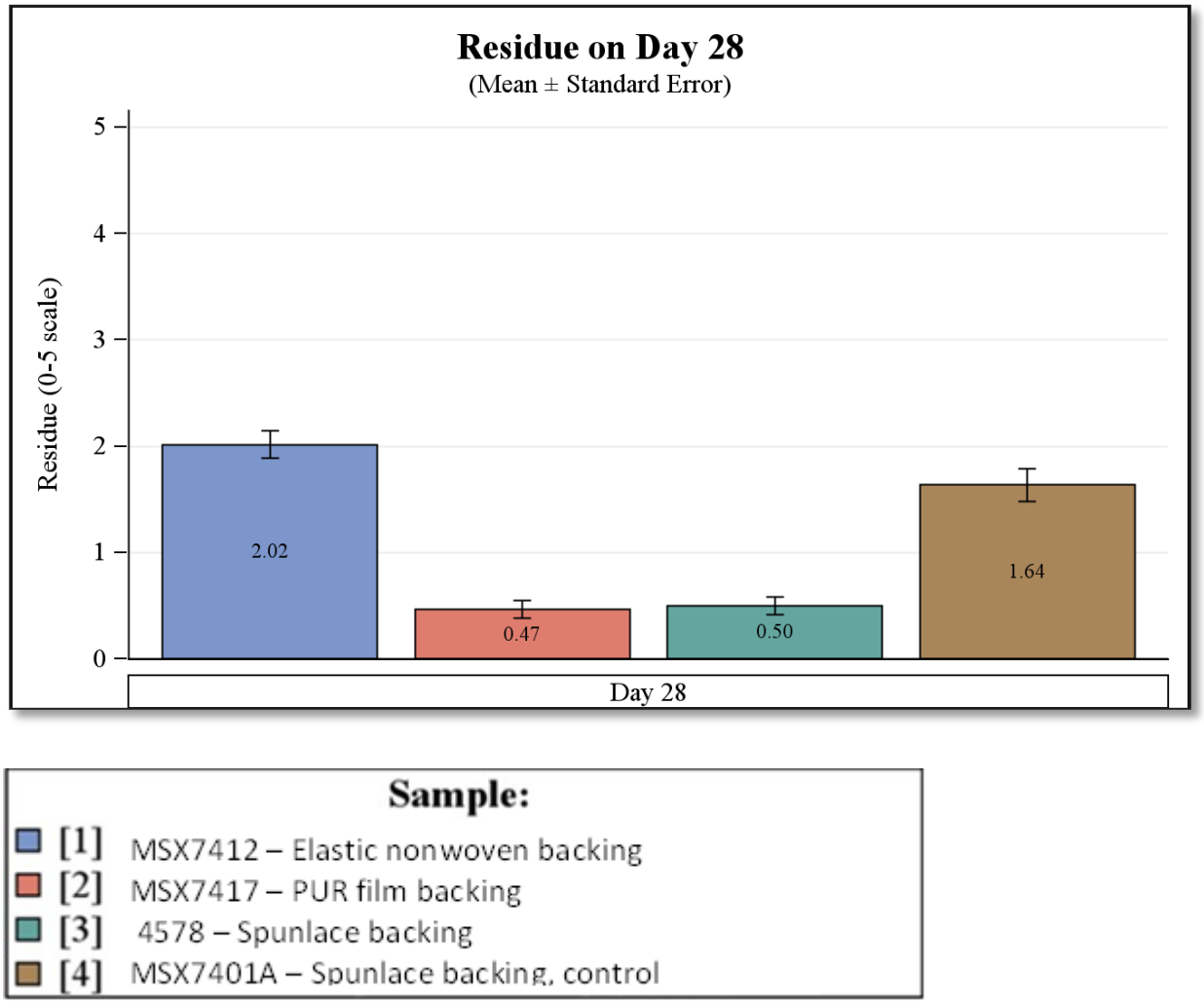



Mean *skirt lift* (lift of the edge around the mock device) was close to 2 for Samples [2], [3], and [4] (range, 1.76−1.87). Sample [1] had significantly more skirt lift than the other 3 samples with a mean skirt lift score of 2.62 at Day 28. *Mock device lift* (lift of the plastic disk from the tape) was minimal for all four samples with mean scores ranging from 0.76 to 0.98 on Day 28, with Sample [2] having the most mock device lift (0.98).

Both overall residue and edge residue were evaluated. For *overall residue*, the mean values at day 28 ranged from 0.47−2.02, indicating some residue for all tapes. Samples 2 and 3 had less overall residue than samples 1 and 4. For *edge residue*, the mean results at day 28 ranged from 1.48 to 3.03, indicating between 25%−75% on average with some higher individual values. Again, samples 2 and 3 had lower incidence of edge residue compared to samples 1 and 4. See figures 4 and 5.

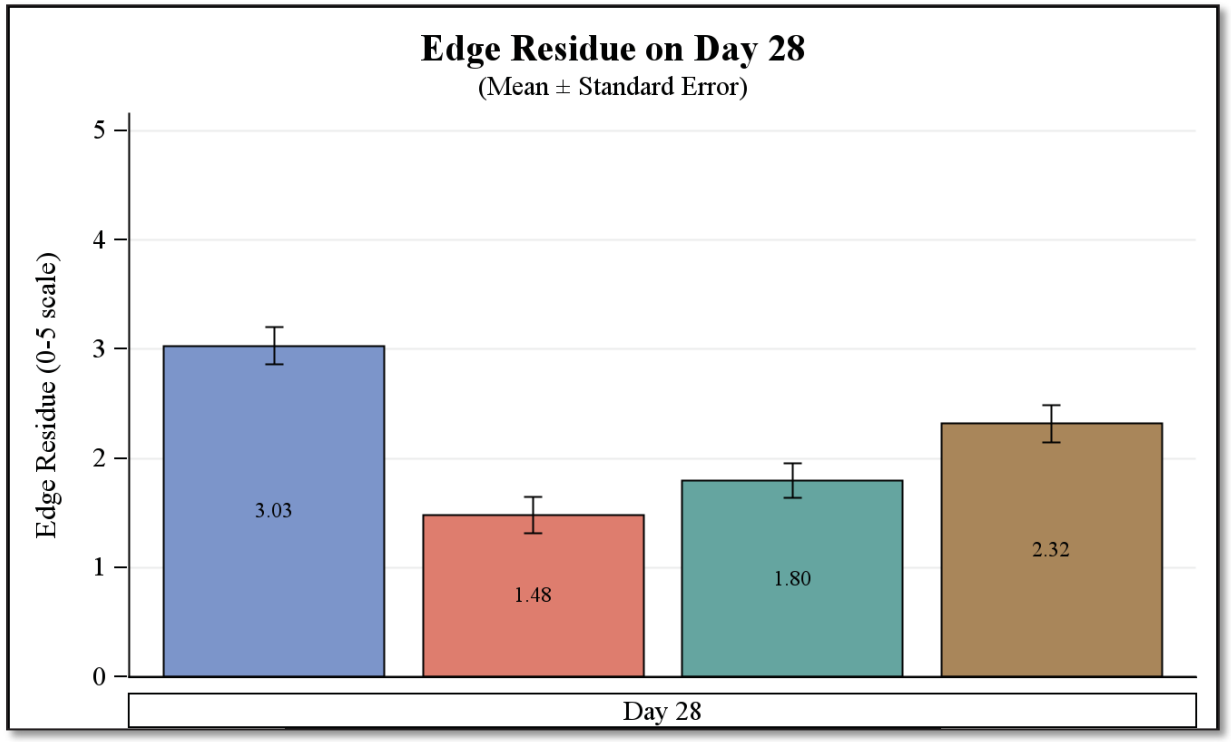
***Figure 4.***

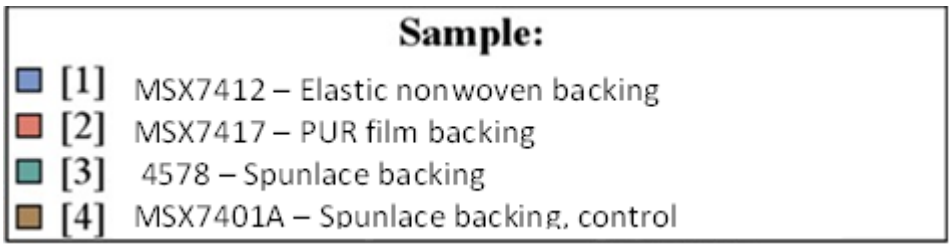
This table illustrates overall residue scores on day 28.



***Figure***

This table illustrates edge residue scores on day 28.




Skin condition was also evaluated after sample removal at 28 days for erythema, edema, skin stripping, mechanical irritation/blistering, and maceration. Lower scores are preferable.

Mean skin assessment scores on Day 28 were generally low for all four samples indicating minimal effects on the skin, with mean scores ranging as follows:

- Erythema on a scale of 0−4 was low, ranging from 1.14−1.30; there were no significant differences between the four samples.
- Edema on a scale of 0−4 was low, ranging from 0.00−0.05; there were no significant differences between the four samples.
- Skin stripping on a scale of 0−4 was low, ranging from 0.06−0.31; Sample [2] had significantly more skin stripping than Sample [4].
- Mechanical irritation/blistering on a scale of 0−3 was low, ranging from 0.00−0.16; Sample [2] had significantly more mechanical irritation/blistering than Samples [3] and [4].
- Maceration on a scale of 0−3 was low, ranging from 0.02−0.53; Sample [1] and Sample [2] both had statistically more maceration after sample removal on Day 28 than Samples [3] and [4].

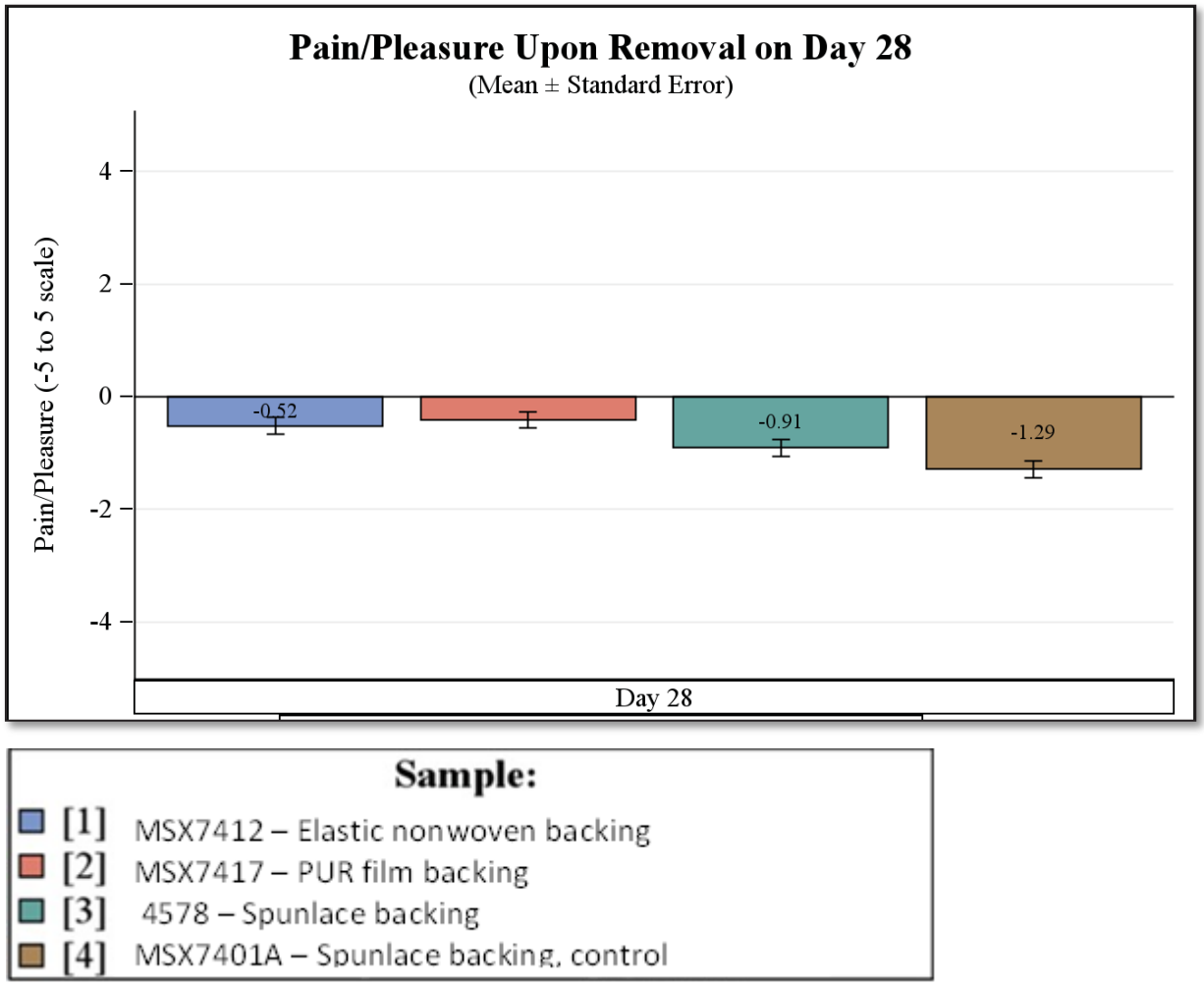
Subject experience (wear comfort, itching, and pain/pleasure on removal) was also assessed. Subjects were asked to rate their wear comfort (scale 0−3) at each weekly visit. On Day 7, test devices on the arms were rated as being either "*very comfortable, forgot they were there*" (score 0, 80.6% of subjects) or "*comfortable but noticeable*" (score 1, 19.4%) for all four samples. Samples were still considered to be very comfortable (score 0) or comfortable (score 1) by the majority of subjects (>96%) on Day 28. Only five individual tape samples were graded as "*uncomfortable but bearable"* during the study. Four individual tapes were graded as being "*extremely uncomfortable*", including three of Sample [2] at Day 14, and one of Sample [1] on Day 28, primarily due to itching.

In the majority of cases (>95%), subjects experienced either no itching or rare to occasional, mild itching. A few incidences of extreme itching were reported for Samples [1] and [2]. Any itching that was extreme/intolerable (severity score 3) or constant (frequency score 3) was also reported as an adverse event.

Pain/Pleasure was assessed by subjects during removal on a scale of −5 (extremely painful) to +5 (extremely pleasant), with 0 being neutral (neither painful nor pleasant). After 28 days of wear on the arms, the majority of subjects experienced either minimal pain (38.7%−62.5% of samples removed with pain scores of −1 or −2) or no pain (25.8%−48.4% with a score of 0) during sample removal. Sample [1] and Sample [2] both had statistically higher pain/pleasure scores on Day 28 than Sample [3] and Sample [4]. Note that a higher (more positive) pain/pleasure score indicates *less pain*. Sample 2 had a single tape sample rated with a pain score of −4; and Sample 4 had four tape samples rated with −4 or −5 for pain during removal at Day 28 (see figure 6).

***Figure 6.***

This chart illustrates the average pain response for tapes at Day 28.



## Discussion and Conclusion

The primary objective of this study was to evaluate the extended wear performance (up to 28 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.

The primary objective of the study was successfully met. Wear−time on the arms was determined to be 28 days for Samples [1] MSX7412, [3] 4578, and [4] MSX7401A, and 26 days for Sample [2] MSX7417 with at least 90% of their samples remaining adhered without failure at those timepoints. Subjects were allowed to shower and perform vigorous activity between study visits. Greater than 60% of patients recorded moderate to very hard activity levels.

A 28−day wear claim would provide an improved health economic advantage, equating to approximately 1 device/month.

The safety of these acrylic−based tapes was also monitored over 28 days. There were 13 mild to moderate, not serious device−related adverse events reported. Most of these reactions included itching, a few cases of mechanical irritation/blistering, broken skin, stinging and one case with dermatitis. All resolved within 17 days and over half within 7 days. These tapes were generally considered comfortable to wear by the subjects throughout the entire study.

A large portion of subjects experienced dry, rough, red scaly skin patches and/or acne, papules, pustules, and/or folliculitis after removal. These skin reactions were anticipated and may be interpreted as a transient effect of long−term occlusion under the tested devices and are expected to normalize within a short period and are not considered to be a safety issue.

When evaluating an adhesive tape component for a project/product, either a medical/retail device or a stick−to−skin product, to adhere to skin, to have the most appropriate tape.

# Acknowledgements


| Role | Contact Information |
|---|---|
| **Project Manager** | Paula Myhre - Clinical Project Manager, Health Care Business Group |
| **Medical Monitor** | Jens Bichel, MD - Associate Medical Officer, Patient Safety, Global Medical Affairs |
| **Biostatistician** | Graham Smith - Biostatistician, Health Care Business Group |



[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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