

Abstract

This study investigates the adhesion performance of DermaFlex™ H-30 and a competitor sample over a 28-day and potentially beyond a 30-day period. The primary objective was to assess the percentage of samples that maintained adhesion throughout the study duration. The results indicate varying levels of adhesion success across the samples, providing valuable insights for product development and optimization.

This study shows that DermaFlex™ H-30 demonstrates better long-term durability than the competitor’s product. While it shows a minor decrease early on, it retains a higher percentage of its original state throughout the study. DermaFlex™ H-30 provides a more reliable and stable performance for applications requiring extended wear, making it a better choice for demanding conditions or prolonged use.

1. Introduction

In the realm of medical devices, the importance of skin-friendly tapes cannot be overstated. These tapes play a crucial role in securing dressings, sensors, and other medical apparatus to the skin, ensuring they remain in place while minimizing discomfort and irritation. The development of skin-friendly tapes has been driven by the need to enhance patient comfort, reduce the risk of skin damage, and improve the overall effectiveness of medical treatments.

Adhesion performance is a critical factor in the effectiveness of patch-based products. This study aims to evaluate the long-term adhesion capabilities of DermaFlex™ in comparison with a market leading competitive product for up to 30 days.

2. Methods

The in-house wear study was performed by applying non-sterile samples (Table 1) on the upper arms (Figure 1) of 18 healthy participants (8 females and 10 males) with an age range from 25 years up to 60 years of age. The age demographics of participants in the wear study significantly impact adhesive wear duration. Younger individuals experience higher rates of cell turnover compared to older individuals, which can lead to a higher likelihood of loss of adhesion over time. The test adhesives were certified for ISO 10993-5 and ISO 10993-10 compliance for skin and body contact. The samples were worn for a 28-day period to assess their durability.

Table 1: Skin Adhesive Constructions

Adhesive ID	Flexcon® DermaFlex™ H-30	Competitor
Adhesive Construction	Polyester non-woven	Polyester non-woven
	Hybrid adhesive	Acrylic adhesive

Participants had the opportunity to wear the samples for an extended period of 28 days (up to 35 days) to explore the potential for longer wear time. The study monitored both the successful adhesion of samples to the skin and the occurrences of failure.

For each sample, the percentage of those that remained adhered by the end of the study was calculated. The adherent status of the patch and the wearing comfort were recorded by the participants daily. Lift percentage was also assessed for each participant according to lift rating scale (Table 2). Skin condition was evaluated upon removal of the samples, and any pain experienced during removal was recorded by the participants at the 28- and >30-day endpoint. The participants were asked to rate their pain on a numeric scale (0-4) with 0 corresponding to “no pain” and 4 corresponding to “severe pain” based on pain rating scale (Table 3).

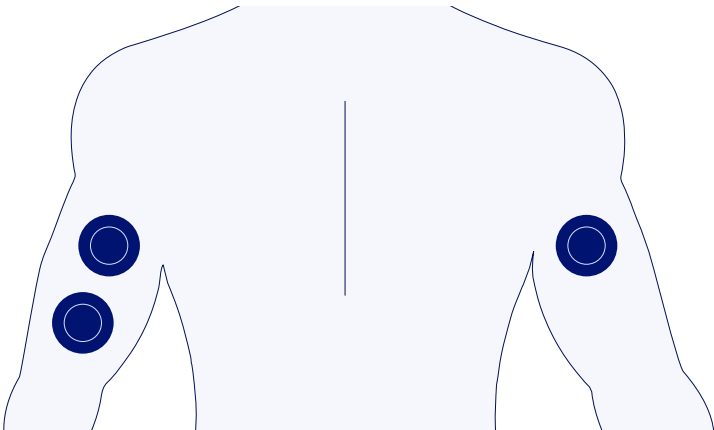


Figure 1

Participants were asked to refrain from applying moisturizers or skin products on or around the patches for 24 hours before attaching the samples and throughout the testing period. Participants were also asked to refrain from swimming, tub bathing, and submersion of samples. No activities were restricted for the 30 days.

Wear Study

3. Results

Table 4 details the status of DermaFlex™ H-30 samples that remained adhered to the skin at 0, 7, 14, 21, 28 and >30 days in comparison to a market leading competitive product. Figure 2 tracks the percentage remaining adhered as a function of wear time. Lift percentage was assessed for all participants and samples, with any sample exhibiting a lift rate above 30% classified as a failure in this study. Among 18 DermaFlex™ H-30 samples, 14 maintained the adhesion, achieving a 78% adhesion rate at 28 days and 66% adhesion rate at >30 days.

Although the competitor starts at 100%, while DermaFlex™ H-30 begins slightly lower at 95%, the competitor's performance begins to decline significantly after day 14, dropping to 56% on day 21 and 50% by day 28.

In contrast, DermaFlex™ H-30 remains stable at 83% throughout this period, indicating better mid-term durability and wear resistance. The competitor continues to degrade, falling to 33%. DermaFlex™ H-30 also sees a slight decline, ending at 67%, but it still maintains a higher retention rate compared to the competitor.

These results suggest DermaFlex™ H-30 demonstrates better long-term durability than the competitor's product. While it shows a minor decrease early on, it retains a higher percentage of its original state throughout the study. DermaFlex™ H-30 provides a more reliable and stable performance for applications requiring extended wear, making it a better choice for demanding conditions or prolonged use. No/low skin irritation was observed for both Flexcon and competitor samples.

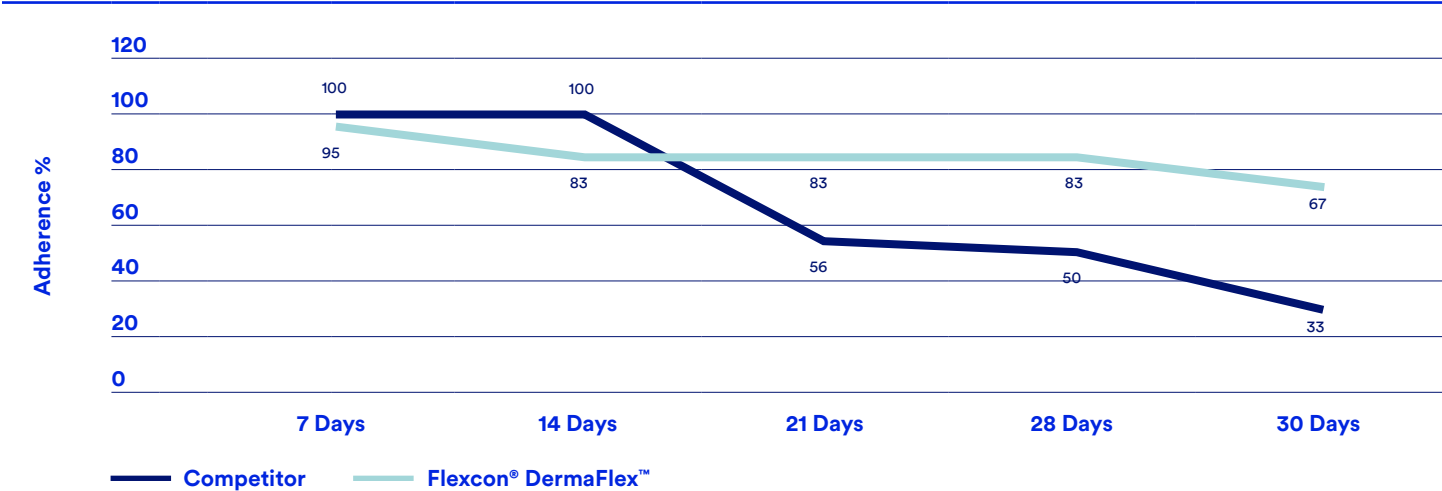
Table 2: Lift Rating Scale

Rating	Lift Level
0	No noticeable lift anywhere on the tape
1	A lift of 10% up to 20% of the area
2	A lift of 20% up to 30% of the area
3	A lift of >30% of the area

Table 3: Pain Rating Scale

Rating	Erythema Level	Description
0	None	No evidence of erythema other than natural skin tone
1	Slight	Barely perceptible increase in light pink coloration, localized or diffuse
2	Mild	Perceptible increase in light pink coloration, localized or diffuse
3	Moderate	Diffuse pink coloration, localized or diffuse areas of reddened skin
4	Severe	Intense redness, diffuse or localized

Figure 2: Wear Time Curves



Wear Study

Table 3

		Flexcon® DermaFlex™						Competitor					
Participant Number	Participant Gender	Test Day 0	Test Day 7	Test Day 14	Test Day 21	Test Day 28	Test Day >30	Test Day 0	Test Day 7	Test Day 14	Test Day 21	Test Day 28	Test Day >30
1	F	●	●	●	●	●	On 31 Days	●	●	●	●		
2	F	●	●	●	●	●	Removed by choice	●	●	●	●	●	Removed by choice
3	F	●	●	●	●	●	Removed by choice	●	●	●	●	●	Removed by choice
4	F	●	●	●	●	●	Removed by choice	●	●				
5	F	●	●	●	●	●	Removed by choice	●	●	●			
6	F	●	●	●	●	●	Removed by choice	●	●	●	●	●	Removed by choice
7	F	●	●	●	●			●	●	●	●	●	On 31 Days
8	F	●	●					●	●	●			
9	M	●	●	●	●	●	On 31 Days	●	●	●	●	●	On 31 Days
10	M	●	●	●	●	●	On 31 Days	●	●	●			
11	M	●	●					●	●	●	●	●	On 31 Days
12	M	●						●	●				
13	M	●	●	●	●		On 31 Days	●	●	●	●	●	On 31 Days
14	M	●	●	●	●	●	On 31 Days	●	●	●			
15	M	●	●	●	●	●	On 31 Days	●	●	●	●	●	On 31 Days
16	M	●	●	●	●	●	On 31 Days	●	●	●			
17	M	●	●	●	●	●	On 31 Days	●	●	●	●	●	On 31 Days
18	M	●	●	●	●	●	On 31 Days	●	●	●			
Total Number Passed		18	17	15	15	14	11	18	18	17	10	9	6
% Adhered		100	94	83	83	78	61	100	100	94	55	50	33

Industry and Application Considerations:

Wear time of medical tape as a leading indicator of performance in skin-worn devices

In the design and deployment of wearable medical devices, adhesive performance is a critical determinant of both device functionality and patient comfort. Among the many metrics used to evaluate adhesive suitability, wear time—the duration a medical tape remains securely attached to the skin—is a leading indicator of overall performance.

1. Wear time as a performance indicator

Wear time reflects the adhesive's ability to maintain skin contact over a defined period, often under controlled conditions. It serves as a primary metric for:

- Predicting clinical reliability (e.g., in long-term monitoring or drug delivery systems)
- Establishing baseline performance standards
- Informing adhesive selection during product development

Longer wear times typically imply stronger adhesion and sustained contact, which are vital for sensors requiring consistent signal acquisition or therapeutics needing controlled delivery.

2. Limitations of wear time alone

Despite its usefulness, wear time in isolation cannot fully represent adhesive performance due to several limitations:

- **Controlled vs. real-world conditions:** Lab-tested wear times may not account for sweat, physical activity, environmental exposure, or skin movement.
- **Static weight testing:** Many tests do not include the additional load introduced by the wearable device itself, which can significantly affect adhesion.

3. Importance of additional testing variables

To ensure robust adhesive performance, testing must expand beyond standard wear time and include:

- **Device weight load testing:** Heavier devices exert greater shear and peel forces, potentially reducing effective wear time or causing premature detachment.
- **Use case simulation:** Applications such as cardiac monitoring, wound healing, or diabetes management differ in their demands—requiring custom testing protocols that mirror expected activity levels, moisture exposure, and reapplication cycles.
- **Environmental and motion factors:** Temperature, humidity, and mechanical skin stress (e.g., bending or stretching) all influence tape performance and must be included in design-stage testing.

4. Skin variability and patient population considerations

Human skin varies widely across individuals, impacting adhesive effectiveness:

- **Age and skin integrity:** Elderly or neonatal patients may have thinner, more fragile skin that is more susceptible to damage or may not adhere well.
- **Skin types and conditions:** Oily, dry, or sensitive skin—as well as conditions like eczema or dermatitis—can reduce adhesive reliability or require special formulations.
- **Body location:** Adhesion on flat areas (e.g., back) differs from dynamic zones (e.g., joints), requiring location-specific evaluation.

While wear time provides valuable baseline data, it does not alone capture the full complexity of real-world use. Additional testing that accounts for device weight, intended application, and diverse patient populations is essential for reliable, safe, and effective design.



Visit flexcon.com/spotlights/dermaflex-nwp-long-term-wear to learn more, view product data sheets, and request samples.

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