

Evaluation of wear time and skin irritation for three medical skin friendly adhesive products - a 21-day study

Abstract

Medical-grade adhesives play a crucial role in clinical settings to secure wearable dressings, devices, and sensors to the skin. They are used in a variety of environments, including hospitals, clinics, and home healthcare. These products are often designed to adhere to skin for extended periods of time.

The wear time of a medical adhesive product is tested and determined by the length of time that it can be worn without becoming loose or dislodged. Skin irritation is also considered when developing and using medical adhesives, and can be influenced by a variety of factors, including the adhesive itself, the skin type of the wearer, and the length of time that the product is worn.

This study aimed to compare the wear time and assess the potential for skin irritation of three different biocompatible medical-grade adhesives (two Flexcon® DermaFlex™ NNRU products, and a competitor product) over a period of 21 days. A total of 27 healthy volunteers participated in the study. The wear time and any signs of skin irritation were recorded at regular intervals. Our findings provide valuable insights into the performance and comfort of DermaFlex™ NNRU (Nylon Netting Reinforced Urethane), a conformable polyurethane film reinforced with nylon netting. DermaFlex™ NNRU, when paired with high-performance Flexcon adhesives, is well known for its high extensibility and strength to secure to the body for prolonged, multi-day use without irritation.

1. Introduction

Ensuring prolonged wear time without causing skin irritation is essential for effective patient care. Several studies have evaluated the performance of brand-specific medical-grade adhesive products, but there is limited research comparing multiple brands over an extended duration. This study aimed to address this gap by comparing the relative wear time and skin irritation potential of three different medical adhesive products: 1) FLX006979 DermaFlex™ NNRU 100 Clear H-566 Spec 50K-9, a high-tack acrylic adhesive with high strength for extended wear, 2) FLX069014 DermaFlex™ NNRU 100 Clear H-778 Spec 50K-8, a high-performance adhesive with ultra-high strength for extended wear, and 3) a competitive commercial solution.

2. Methods

2.1 Participants

A total of 27 healthy adult volunteers (8 males, 19 females) aged between 20 and 64 years were recruited for the study, 21 of whom completed testing. Participants with a history of skin disorders, allergies or sensitivities were excluded from the study.

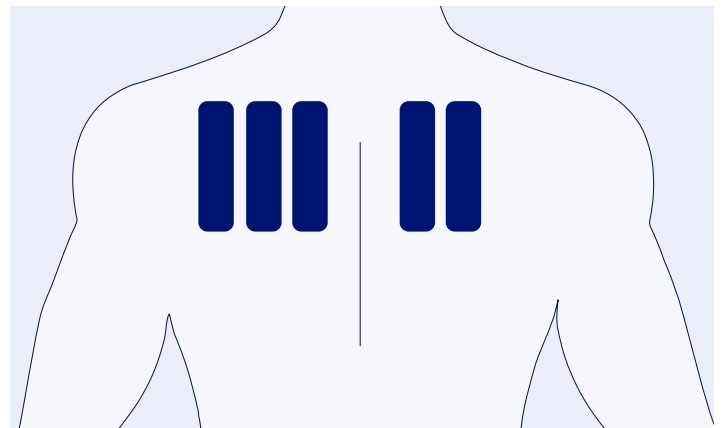
2.2 Products

Three medical adhesive products were selected for evaluation: FLX006979, FLX069014, and a competitive commercial solution claiming extended-wear properties.

These products were chosen based on their well-established and widespread use in clinical settings. Each product was applied to a designated area on the upper back of each participant, following Flexcon's protocol instructions.

2.3 Study Design

The study was conducted as a single-blind, randomized controlled trial by an ISO/IEC 17025:2017 accredited third-party clinical testing laboratory. Each participant had all three products applied to separate areas on their backs, ensuring a balanced distribution of products across the participants. The order of product application was randomized for each participant to mitigate potential biases.



Product placement location examples.

2.4 Wear Time Assessment

The wear time of each product was recorded individually using a standardized protocol. Participants were instructed to avoid sunbathing, tanning beds, swimming, and soaking in pools or tubs, as well as to shower forward-facing only, and not to scrub or apply anything to test sites during the study period. The time of detachment for each product, if any, was noted, and the cumulative wear time was calculated using the following scale:

Wear Study

2.5 Skin Irritation Evaluation

Skin irritation was evaluated at regular intervals by trained healthcare professionals. An adverse events scoring system was used to assess the severity of skin irritation. A score of 0 indicated no irritation, while scores ranging from 1 to 4 represented increasing degrees of irritation as shown here:

3. Results

3.1 Wear Time Comparison

The cumulative wear time of the three medical adhesive products over the 21-day study period indicated that all under tests, FLX006979, FLX069014, and the leading competitive solution, achieved a Skin Assessment industry-acknowledged “passing” score of 3 or lower (i.e., 50% or more adhesion at 21 days).

3.2 Skin Irritation Assessment

The Skin Irritation scores for each product over the 21-day study period indicated that DermaFlex™ FLX006979 had the lowest incidence of skin irritation, with a maximum score of 0.5 in only one participant. DermaFlex™ FLX069014 exhibited a slightly higher incidence of skin irritation, with scores ranging from 0.5 to 1 in two participants. The competitive product displayed the highest score of skin irritation, with scores from 0.5 to 1 in three participants. All products tested were deemed “non-irritating” by the testing laboratory based on these scores.

Grade	Description
0	No evidence of any effect
0.5	Barely perceptible; minimal faint (light pink) uniform or spotty erythema
1	Mild; pink uniform covering most of contact site
2	Moderate; pink/red erythema, uniform in entire contact area
3*	Marked; bright red erythema with accompanying edema, petechiae or papules
4*	Severe; deep red erythema with/without vesiculation or weeping

Score	Skin Assessment
1	≥ 90% adhered
2	≥ 75% to < 90% adhered (some edges only lifting off the skin)
3	≥ 50% to < 75% adhered (less than half of the system lifting off the skin)
4	< 50% adhered but not detached (more than half the system lifting off the skin without falling off)
5	Patch is detached (completely off the skin)

4. Discussion

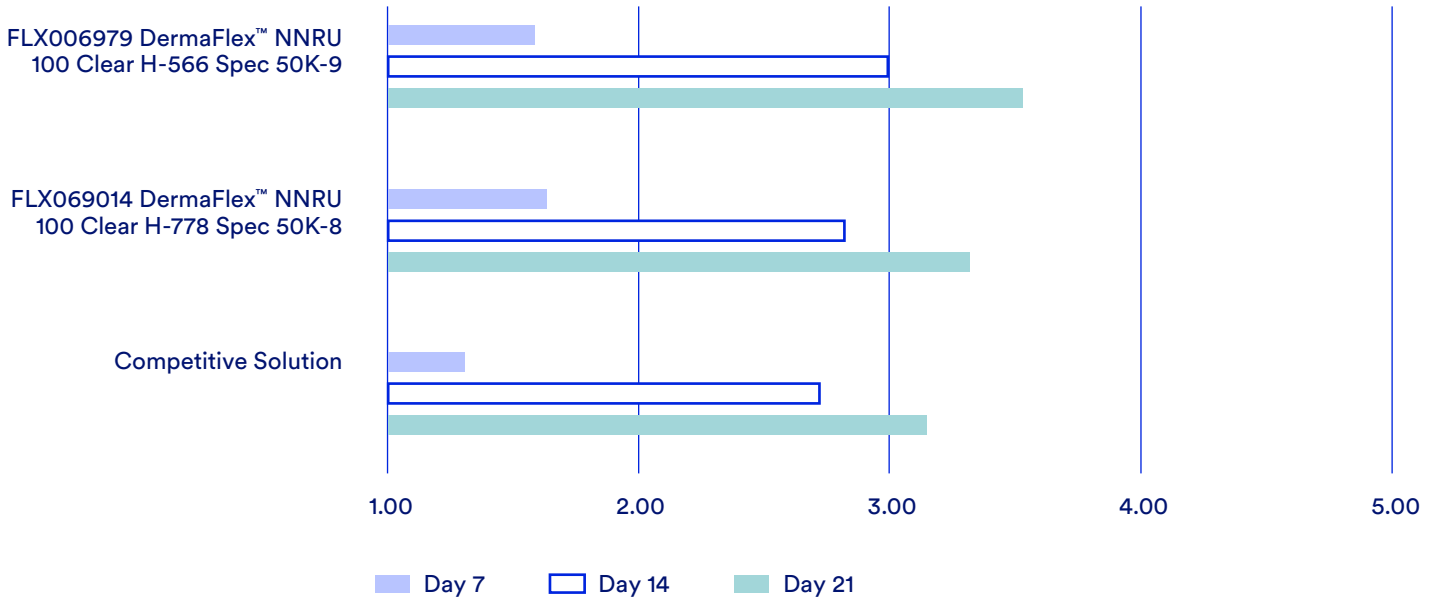
The findings of this study demonstrate the utility of the DermaFlex™ extended wear time medical adhesives in balancing effective skin bonding while balancing other critical properties such as skin irritation and patient comfort. Wear performance results of these DermaFlex™ adhesive technologies showed both were non-irritating to skin and performed equivalently to that of the market competitor for 21-day wear. These DermaFlex™ solutions may be of interest to device manufacturers seeking high-performance, skin-friendly technologies that are highly customizable in film and adhesive selection to meet their unique design criteria. DermaFlex™ NNRU (Nylon Netting Reinforced Urethane) with a variety of biocompatible skin contact adhesives provides a high-tack, yet thin and lightweight, flexible, and breathable adhesive designed to move with the body and provide long-term, 21-day adhesion without irritation.

Conclusion

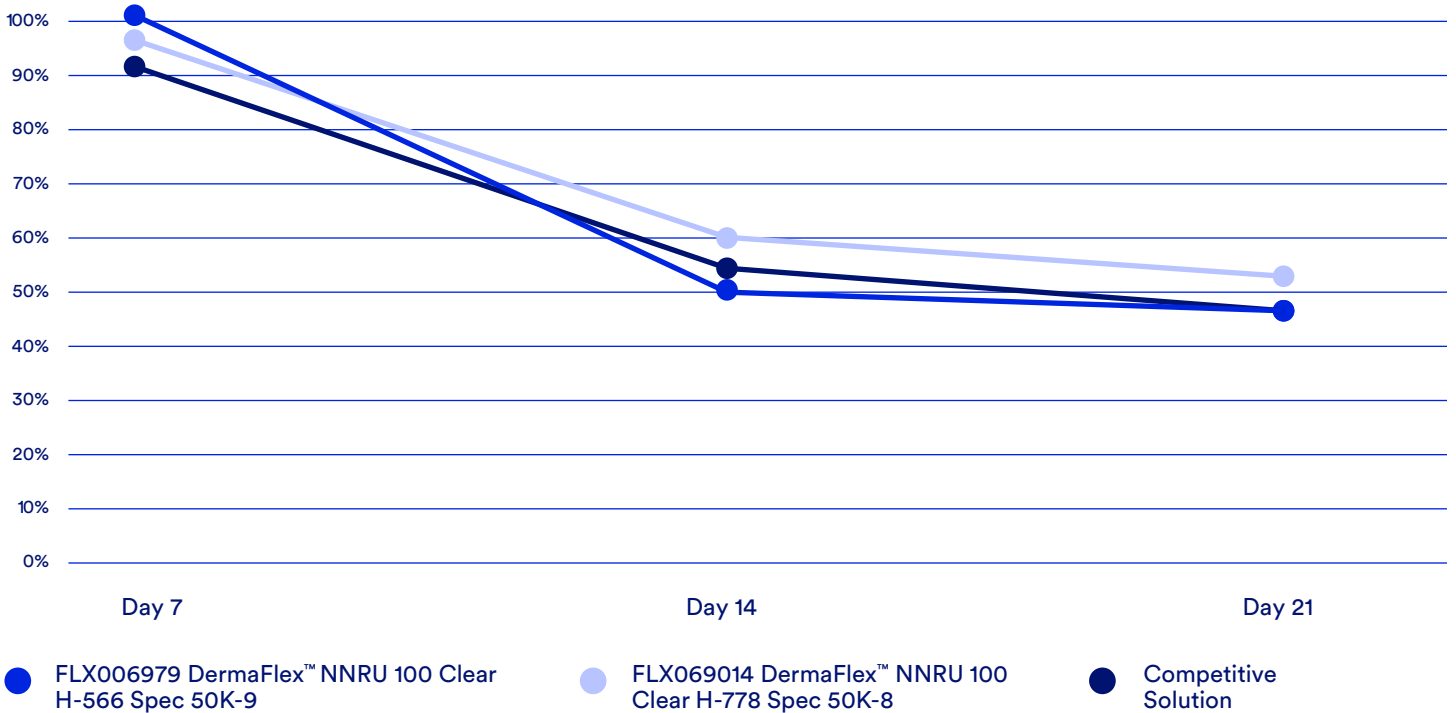
DermaFlex™ NNRU products can confidently be used for applications that require adhesion to the skin for an extended period of time. Additionally, the DermaFlex™ portfolio uniquely offers a wide variety of finished formats for every application, fueled by cutting-edge materials science expertise. This means that both converters and OEMs alike can be sure that with DermaFlex™, they're using the most innovative and versatile medical adhesives for their exacting device requirements.

Adhesion Evaluation Score (Mean)

A score of 3 or lower indicates at least 50-75% adhered



Percent of patients reporting an adhesion evaluation score of 3 or lower





In 1956, Myles McDonough pioneered the first pressure-sensitive film product in a Spencer garage, breaking away from the industry's focus on high-volume commodity products. His vision was to meet the unique needs of innovators seeking new applications for pressure-sensitive films.

Today, over 65 years later, Flexcon continues this legacy, serving diverse industries such as packaging, electronics, transportation, and healthcare. Flexcon is a trusted manufacturing partner, known for turning innovative ideas into reality. For over 35 years, Flexcon has been supplying the healthcare industry with adhesives, tapes, films, and coating technologies. Our products support applications in patient care, pharmaceuticals, diagnostics, and consumer wellness.

DermaFlex™



Visit www.flexcon.com/dermaflex to learn more, view product data sheets, and request samples.

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