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MEDICAL TECHNOLOGIES

# MED 5750A

## Wear-time comparison of three pressure-sensitive acrylic skin adhesives

*Case Report*

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*Inspired Advances.*
*Intelligent Results.*

# Wear-time comparison of three pressure-sensitive acrylic skin adhesives


## Abstract/Executive Summary

This study's aim was to quantify and understand the adhesive performance of acrylic pressure-sensitive skin adhesives when used in a prototypical wearable device worn on the back of the arm. Three different skin adhesives were tested in similar product constructions: MED 5750A, which is increasingly being favored in wearable applications, was compared to MED 5769A and MED 5725P which are similar in construction, but use adhesives optimized for use in wound care and ostomy applications, respectively. The primary efficacy end point of interest was total wear time and secondary endpoints of interest were adhesion percentage and comfort level. Data from participants were collected via telephone interviews. Results from this comparative study showed that the acrylic skin adhesive used on MED 5750A, reliably yields a 7-10 day wear time and was superior to both MED 5769A and MED 5725P in this regard. The results emphasize the importance of selecting the right adhesive for the right application.


## Introduction

Wearable, flexible medical devices, such as glucose monitors, biotelemetry devices, and the like, are gaining traction with increased usage as they have applications in both fitness monitoring and medical diagnostics. Recent advances in wireless technologies and low-power electronics are powering innovations in wearable medical devices at a tremendous pace (1). To be efficacious, these devices must be kept in reliable interface with the user's body, and thus choosing the right adhesive is essential for proper performance. It is advantageous to achieve long wear times, partly from a user convenience point of view and partly to extract the maximum economic value out of costly medical devices. Choosing the right level of adhesion is particularly important for skin-contacting consumer products and medical devices because there is a need for a careful balance between secure attachment and easy removal. Inappropriate selections can lead to adhesive failure or skin injury.

Pressure-sensitive adhesives (PSAs) are polymeric materials that adhere to a variety of substrates through cohesion and adhesion when applied with pressure. The characteristic properties of these adhesives are i) tack: ability to adhere quickly, ii) peel (adhesion): ability to resist removal by peeling and iii) shear (cohesion): ability to hold in position in presence of shearing forces (2).PSAs for stick-to-skin medical applications are required to perform a wide range of functions under various conditions on a complex substrate. PSAs for skin should possess several requisite traits including high tolerability with minimal allergic potential, good skin adhesion, optimal release, good water resistance, breathability, etc. (3).

Several kinds of polymeric raw materials (rubbers, silicones, acrylics, polyether, polyesters, polyurethanes and ethylene-vinyl acetate-copolymers) can be used to formulate PSAs. Acrylic PSAs are ideal for stick-to-skin applications due to their unique combination of high tackiness, high cohesion, high stickiness, ultraviolet and hydrolysis resistance, solvent and temperature stability and optical clarity. Acrylic PSAs are also considered to be more cost-effective when compared with silicone PSAs and polyurethane PSAs (4).

Acrylic skin adhesives are increasingly being used for long-term wear applications, especially in skin adhering wearable devices. This adhesive is applied to a nonwoven backing material to produce MED 5750A. Two other products, MED 5769A and MED 5725P, are very similar in construction but utilize different PSAs: MED 5769A uses Thin Absorbent Skin Adhesive™ (TASA™), which has been optimized for use in wound care, and MED 5725P uses a porous acrylic adhesive, which has been optimized for use in ostomy applications. This evaluation was undertaken to determine and compare wear times of these three products featuring different acrylic PSAs when used to secure a wearable monitoring device to the skin.

# Methods

### Materials:

All three products used for the study feature pressure-sensitive acrylic skin adhesives on a nonwoven backing. MED 5750A uses an acrylic skin adhesive and commonly finds application in the wearable device market. Two other products with similar constructions are MED 5769A and MED 5725P, which use adhesives optimized for use in wound care and ostomy applications, respectively. Table 1 and Figure 1 show the comparative physical properties of these three products. Table 2 compares the three different products' materials and layer constructions.

A prototypical wearable device was constructed in three different versions, each the same size and shape (Figure 2) but using the three different adhesives as the skin-contacting layer. The devices incorporated physical activity and lifestyle monitoring capabilities, including measurements of energy expenditure intensity and duration, steps taken, and sleep patterns. The devices measured 4.5 inches x 2.5 inches in size and weighed 12g approximately. The devices were assembled by mounting the electronic module to a larger, ovoid piece of either MED 5750A, MED 5769A, or MED 5725P, as illustrated in Figure 2.

**Table 1: Physical properties of the three products that were compared**

| Property | TDS Test Method | MED 5750A | MED 5769A | MED 5725P |
|---|---|---|---|---|
| Peel Adhesion on Polyethylene (PE) [N/25mm] | TDS-01 | 3.5 | 1.0 | 3.5 |
| Peel Adhesion on Stainless Steel (SS) [N/25mm] | TDS-05 | 1.5 | 0.5 | 4.5 |
| Static Shear [min] | TDS-12 | 130 | 90 | 20 |
| Finat Tack [N/25mm] | TDS-07 | 10.0 | 4.5 | 10.0 |
| MVTR [g/m$^2$-24hr] | TDS-16 | 650 | 1300** | 1800 |

** MED 5769A features a unique PSA which, unlike the other two products, is capable of both breathability and fluid absorption. When the adhesive's static absorption is considered together with its MVTR, MED 5769A has a total fluid handling capacity of approximately 2,000 g/m$^2$-24hr.

**Figure 1: Spider chart showing the relative physical properties of the three products tested**

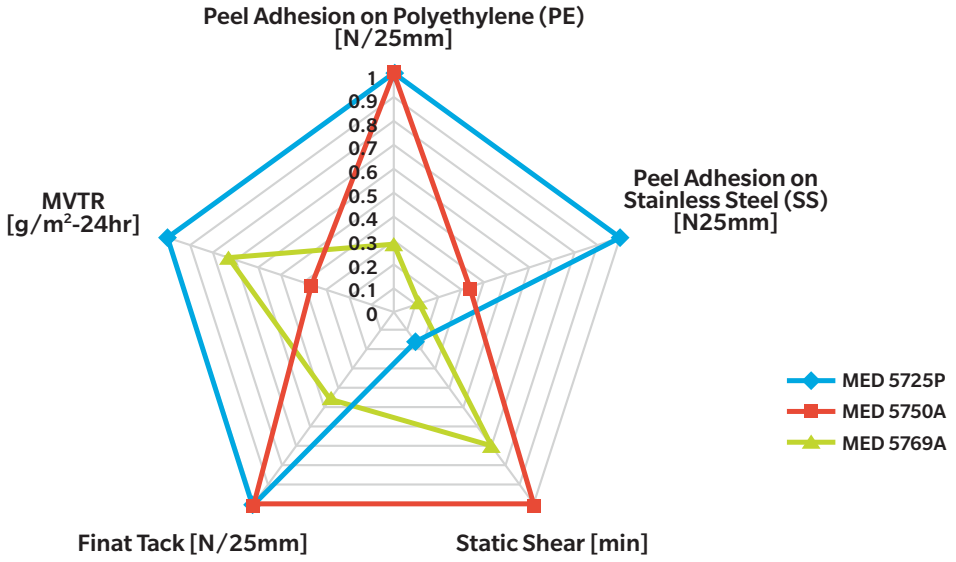
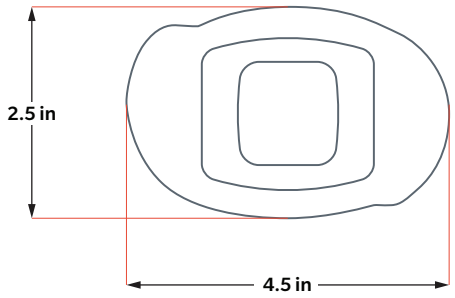



**Table 2: Comparison of the three skin adhesive products' constructions**

| | MED 5750A | MED 5769A | MED 5725P |
|---|---|---|---|
| Carrier | 500 µm Polyethylene Nonwoven | 500 µm Polyethylene Nonwoven | 600 µm Polyethylene Nonwoven |
| Adhesive | 60 µm acrylic adhesive | 100 µm TASA | 50 µm porous acrylic adhesive |

**Figure 2: Illustration of the prototypical wearable devices that were built using the three different skin adhesive products**




## Methodology:

The study was conducted in a single center on healthy human volunteers in compliance with Good Clinical Practice (GCP) Regulations. Participant's consent was obtained prior to enrollment in the study.

**Eligibility criteria:** Subjects were screened by pre-determined inclusion and exclusion criteria. The inclusion criteria were: i) Adults of age 18 to 65 years and in good health, ii) willing and able to follow study directions, iii) willing to refrain from taking showers or engage in strenuous physical activity for at least 3 hours after the devices are applied to the skin, and iv) agrees to be available for daily telephone interview. Exclusion criteria were: i) pregnant women, ii) acute or chronic illness, iii) immunocompromised subjects, iv) use of any prescribed anti-inflammatory drugs, immunosuppressive drugs or antihistamine medication, v) current participation in any other clinical testing or investigational drug study, vi) allergy to adhesives or bandages, and vii) damaged skin in or around test sites.

**Baseline measurements and application site preparation:** Subjects were asked to visit the research facility on Day 1 and Day 10. On the day of initial visit (Day 1) subject's biometrics were measured and recorded. This included participant's age, gender, height, weight etc. The subjects wore the three variants of the prototypical wearable devices for up to 10 days. All devices were worn on the backs of the upper arms. Prior to the application of the devices, the test site skin was cleaned with alcohol wipe (70% isopropanol) and left to dry for at least 2 minutes. Sensors were marked with unique subject identification code which also included a code to identify the location of device placement as well as the test article identification code. Placement of the sensors with skin adhesives on each body location was randomized such that sensors with specific skin adhesives were equally distributed over the left and right arms, and over the upper and lower locations.

**Daily assessments:** From Day 2 to Day 9, subjects completed a daily survey phone call to capture their qualitative observations regarding adhesion of the devices and comfort. Subjects were asked about each prototype, if the device is still adhered to the body or if it had debonded or removed. For any device still adhering to the body, the subjects were asked what percentage of the device surface was no longer adhering to the skin in 25% increments (i.e. 0-25% debonding, 20-50% debonding, or >50% debonding). If the device was no longer adhered to the skin, the subject was asked at what time the device came off.

Total wear times were calculated for each prototype for each subject. Where a device had fallen off prior to removal on Day 10, the date, time and conditions under which the device came off were documented. Total elapsed wear times were computed for each device based on the best available information documenting the removal time, which in most cases was data logged by the device itself. Total wear time was defined as the elapsed time from the moment the device was applied until it became detached from the skin either intentionally or unintentionally. Telephone interview responses and assessment logs were used to establish whether the devices were removed intentionally. Subjective assessments of comfort of wear were also made for each prototype, for each subject. Patient discomfort scale variables included itching, burning, tingling, soreness and any other discomfort. Each variable on this scale was rated by each participant as 0 = None, 1 = A little bit (noticeable but not bothersome), 2 = Moderate (bothersome but tolerable) and 3 = A lot (not easily tolerated).

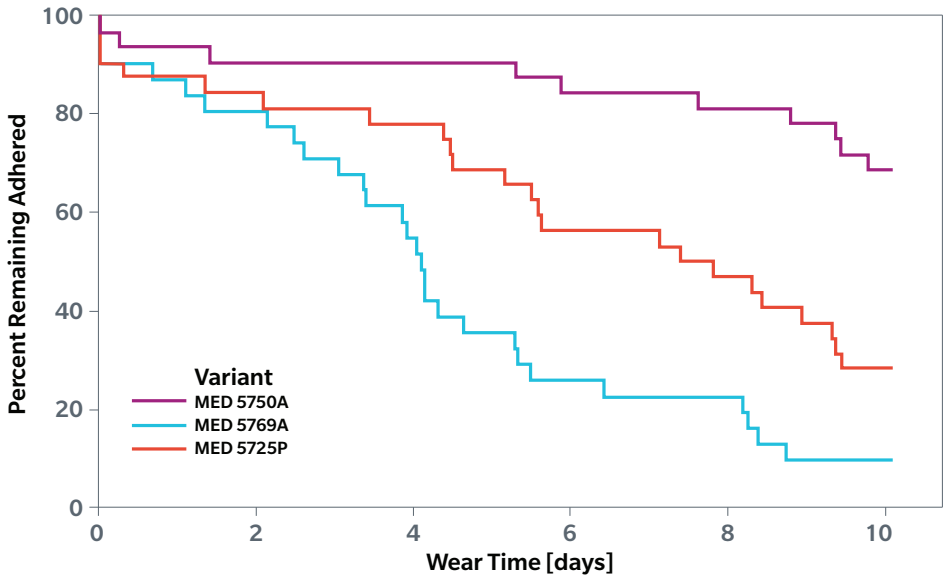
**Statistical analysis:** Data was tabulated and basic summary statistics (mean and 95% confidence intervals (CIs) were calculated. Survival analysis was conducted using Minitab® statistical software (Minitab, Inc., version 16.2.4). Non-parametric Kaplan-Meier technique was used to generate survival curves from the available data.

# Results

Thirty-five subjects signed the informed consent and were enrolled in the study. 34 subjects (28 females and 6 males) completed the study and were included in the analysis. The participants were between 25 and 63 years old, with a median age of 50.1 years (mean age of 48.1 years). Their BMIs ranged from 19.4 kg/m² to 45.2 kg/m², with a median BMI of 29.3 kg/m².

**Wear times:** The total number of days each variant was attached to the arm was computed as the elapsed time between the device application and removal, as logged in the evaluation forms or assessed by analysis of the device's data logs. Of the three products tested, MED 5750A yielded better wear times on the arm than either MED 5769A or MED 5725P (Figure 3). Pairwise comparisons made between each of the survival curves confirmed the statistical significance of the superiority of MED 5750A vs MED 5769A ($p<0.001$) and MED 5750A vs MED 5725P ($p=0.001$).

**Figure 3: Survival curve illustrating the percentage of devices that remained adhered as a function of the duration of wear time.**




**Patient comfort:** 33 participants (97%) reported no itching, burning or any other discomfort at any point of time. One participant reported mild itching (Grade 1) on day 7 for MED 5769A. None of the other participants reported any form of discomfort.

# Discussion

Advances in pressure-sensitive skin adhesive technology have a direct impact on widespread usage of wearable health monitoring systems in healthcare. Advanced adhesives are associated with improvements in one or more of the following characteristics: conformability, stretchability, breathability, porosity, absorbency, and durability. Selecting the right adhesive which provides kinder, gentler adherence to skin with long lasting bonds for extended wear is critical in realizing both clinical and economic targets in wearable device applications.

MED 5750A features a medical grade acrylic adhesive designed for long-term wear applications. The adhesive's properties are optimized to meet the demands of multi-day wearable devices applications, and this was evidenced by its superior performance in comparison to MED 5769A and MED 5725P. Neither of those products was engineered to meet the demands of the wearable device market. MED 5750A was found to have longer wear times and increased adhesion levels on healthy, intact skin. Products like MED 5769A and MED 5725P may, by nature of their design and properties, be more suited for use on damaged/fragile skin sites. The Thin Absorbent Skin Adhesive used in MED 5769A has, for instance, been demonstrated to offer unique advantages over conventional PSAs when used in advanced, filmic wound dressings. (5,6).

# Conclusion

This healthy human wear duration study compared the abilities of three different pressure-sensitive adhesives to secure a prototypical wearable device to users' skin over a 10-day period of time. MED 5750A, a product specifically engineered to provide long, durable wear times, performed better than the two comparator products, emphasizing the importance of selecting adhesives that are custom tailored to achieve desired performance characteristics.

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