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Designing Wearable Devices for Fragile Skin

Medical Materials & Technologies

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Introduction

Wearable devices worn on skin are becoming more prevalent as medical diagnostics and analytic platform technologies advance, become smaller, smarter and more assessable to point-of-care settings. What used to require a hospital stay may now be done remotely, using a small wearable body patch. No need to be hooked up to machines wearing open air hospital gowns. For example, if an individual needs to monitor their cardiac health, today a patient may be prescribed to use an electrocardiogram (ECG) patch as an outpatient, which is worn on the upper torso, tracks heart rhythm, and thanks to wireless technology, transmits the trace data in real-time from the comforts of the end user's home directly to their healthcare provider.

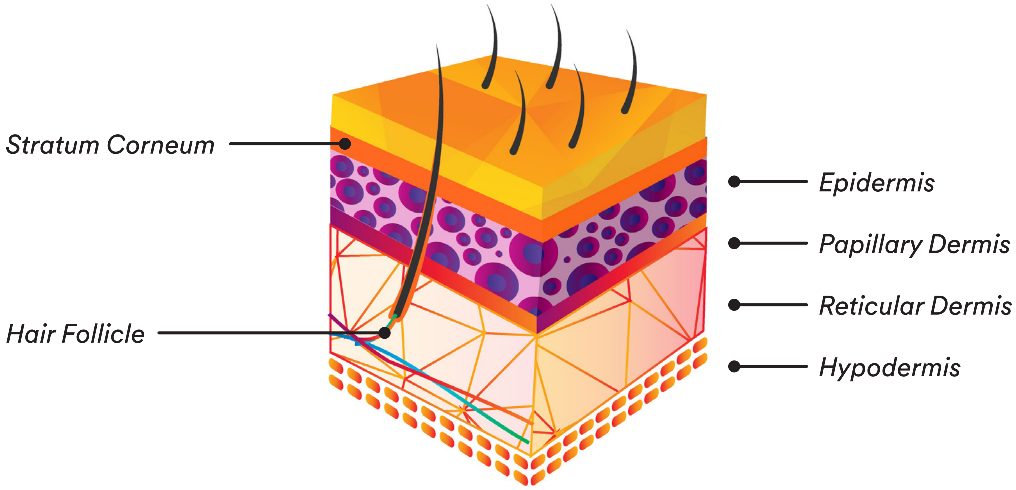
Success of stick to skin wearable monitoring devices relies heavily on accuracy, design and the device's secure attachment to the body throughout the required wear time. An advantage of adhering a device directly to skin is it creates an intimate interface between the device and the skin. Other methods that must be mechanically attached with various fixturing, are less discreet, can interfere with clothing and limit the end user's range of mobility. Example fitness trackers may need uncomfortable tightening to maintain contact and stay in place during vigorous workouts. Adhering to skin is a method we are all familiar with, bandages and first aid dressings are a rite of passage for most children.

Fortunately, skin is something we all have in common. Although universal in form, skin can be very diverse across a population, with factors such as genetics, age and health contributing to the range in variations.

The influence of skin is a major factor in the design and performance of a wearable device, which often gets overlooked. This paper will discuss design considerations of wearable devices with a focus on adhering to fragile skin. Before delving into design considerations, we'll review a brief background on skin and indications of fragile skin.

A Brief Background on Skin

Skin is the body's glove. It protects internal organs, regulates our body temperature, allows for sense of touch and feel, and is a vital part of our external identity. Throughout one's lifetime, skin will continuously evolve and change. It continually sheds the stratum corneum, the outermost layer comprised of dead skin cells, replacing it with new cells. On average, the skin sheds and replaces itself every 14 days.



The cycle of cell renewal reduces with age, along with other effects such as reduced moisturization, leading to dry skin and thinning of the skin, which increases fragility.

Indications of Fragile Skin

Fragile skin conditions can affect everyone. Physiological factors, such as the skin's location on the body, like face and eyelids, play a large role. Age is another key factor, with people on the opposite ends of the age spectrum –infants and elderly adults – being most at-risk for injury.

Infant skin is fragile because the epidermis layer is thinner and still maturing, a process that continues over the first year of life.[1] On the other side of the spectrum, elderly skin is fully mature, and with time becomes thinner and loses moisture, becoming more fragile.

Fragile skin can be divided into four categories

Physiological

- Infant skin, elderly skin and fragile zones, such as the face and eyelids

Pathological

- Acne, atopic dermatitis, rosacea

Circumstantial

- Environmental: Skin aggressed by climatic stress (heat, cold), chemicals
- Mechanical: Rubbing

Latrogenic

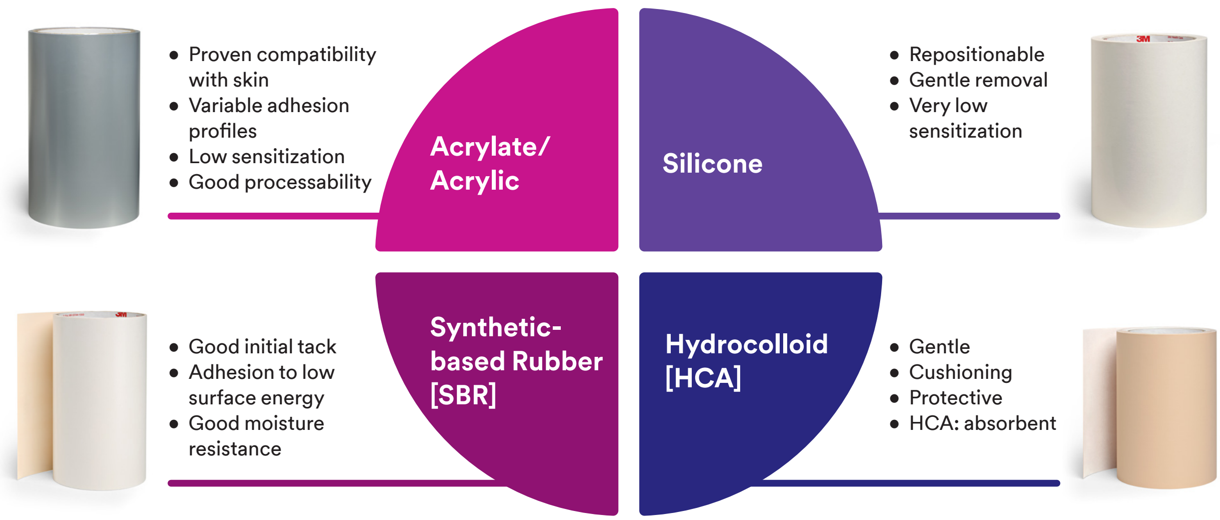
- Medicinal treatment, aesthetic procedure[2]

When it comes to adhering a device to skin, When it comes to adhering a device to skin, particularly fragile skin, it cannot be approached like adhering to static substrates, such as glass, polymers or metal. Skin is a living, dynamic organ that is continuously changing throughout the course of the device's wear time.

Medical Adhesive Options

There are three main categories for stick to skin pressure sensitive adhesives (PSA) for wearables: **acrylic/acrylate, silicone** and **synthetic rubber**. In addition to the main three categories, there are various other specialty formulations such as hydrogels, which are conductive, and **hydrocolloids**, designed for wicking moisture, as well as many other modified adhesive polymers for specific applications too numerous to cover here (but we'd be happy to discuss them with you outside of this).

Medical Grade Adhesives Categories



Synthetic rubber-based adhesives have strong adhesion properties to low surface energy materials. Because of their strong bonding properties, they are often the first choice for bonding construction layers within a device rather than the stick to skin layer.

Comparison of Acrylate and Silicone Adhesives: Features and Benefits

The two most common adhesives used for stick to skin applications are acrylate and silicone.

Acrylate adhesives have been the go-to choice for stick to skin applications for many years. This is because acrylate adhesives have a long linage of success on skin. They are skin friendly, easy to manufacture and convert into finished parts, can be formulated to a virtual range of adhesion levels, and are stable over time.

Features generally include:

- Gentle to strong bonding
- Can be formulated for wide range of adhesion levels
- Adhesion builds over time
- Easy to handle, convert and assemble
- Cost-effective
- Short to long wear time

Silicone adhesives are a newer option for stick to skin adhesives, known for their gentle adhesion, inert chemistry, and pain-free removal. This class of adhesives is quickly becoming the go-to choice for gentle skin applications.

Silicone adhesives have inherently different physical properties which enhances their behavior both in application and removal, making them perfectly suited for fragile skin applications.

Features generally include:

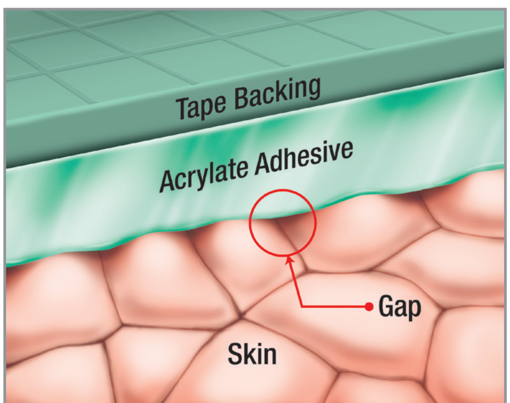
- Gentle to moderate bonding
- Stable adhesion overtime
- Water resistant
- Inert, less interaction with skin & hair
- Very conformable
- Short to moderate wear time

Comparison of Acrylate and Silicone Adhesives: Application to Skin

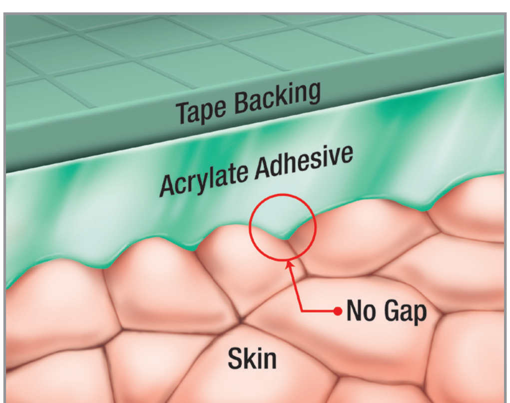
Traditional acrylate adhesives require higher adhesion because they are slower to "wet out" and conform to the natural profile of the skin, initially adhering to the skin's highest points. With time, the adhesive will flow into the contours of the skin and around hair, increasing adhesion and possible pulling when hair and the stratum corneum layer are removed with the tape.

Silicone adhesives have low surface energy and, more importantly, low modulus, which allow the adhesive to quickly wet out, forming a maximum bond. They are more elastic than traditional acrylic adhesives, especially at a long timescale. This eliminates the cold flow of the adhesive around hair and skin cells.

Traditional acrylate adhesives

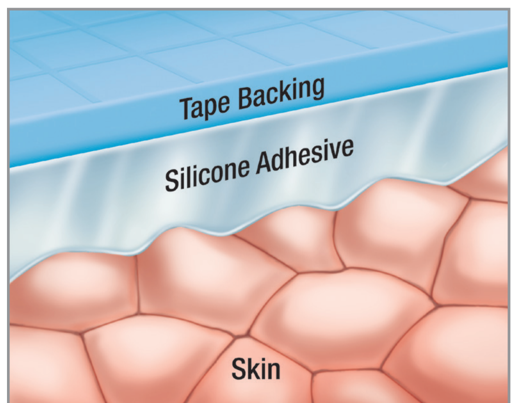


Initial Application of Conventional Acrylate Adhesive Tape

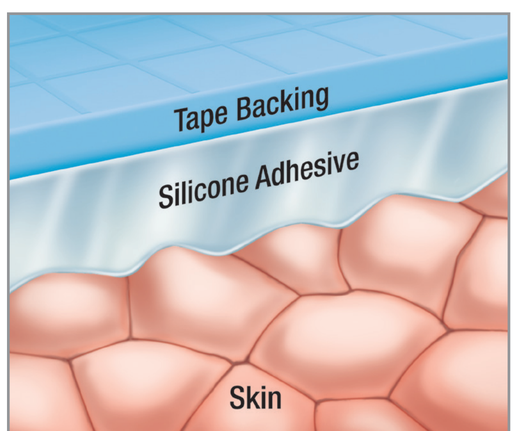


Conventional Acrylate Adhesive Tape with Time

Silicone adhesives



Initial Application of Silicone Adhesive Tape



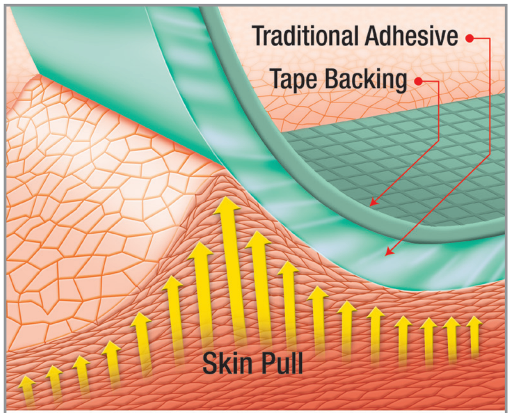
Silicone Adhesive Tape with Time

Comparison of Acrylate and Silicone Adhesives: Removal from Skin

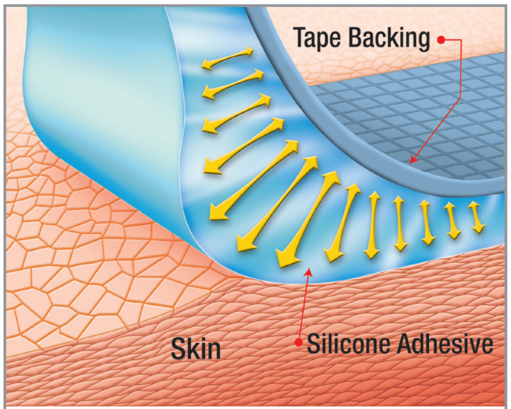
The below illustration demonstrates the advantage of silicone adhesive properties compared to traditional acrylic adhesives during removal from the skin.

Acrylate adhesives are stiffer and display less deformation, resulting in greater skin pull during removal.

Silicone adhesives have a lower modulus than acrylates, as stated before, which deforms upon removal, resulting in less trauma and disruption to the stratum corneum layer of the skin.



Removal of Traditional Adhesive Tape



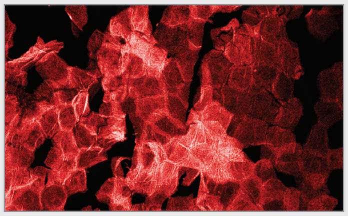
Removal of Silicone Adhesive

Results may vary based on application

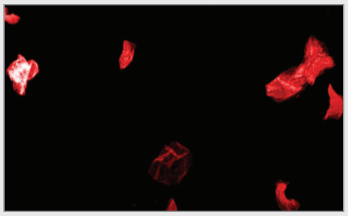
Transfer of stratum corneum cells to adhesive during removal

The confocal microscope images below are medical tape adhesive surfaces after being removed from a healthy volunteer. The images show skin cells and hair in red that were stripped off during the removal of tapes.

Results show a qualitative difference between silicone adhesive and traditional acrylate adhesive on skin cell removal.



A. Traditional Acrylate Adhesive



B. Silicone Adhesive

Design Considerations: How to apply the science of fragile skin to your device design

Before choosing an adhesive that will work best in your device, it is critical to develop a full and complete understanding of the device, its construction, components and the application, and end user requirements. The finished device and all of its parts need to work in unison.

Below are five key question to consider when designing a stick to skin device.

1. What is the application?

Applications can vary widely, from a simple one-hour disposable temperature monitor, a one- to two-day drug delivery or pain management device, or a more demanding two-week wear time application, such as a continuous glucose monitor (CGM) that monitors critical body chemistry data to manage lifesaving insulin doses.

Developing a clear understanding of each component's requirements and how all of the device's components interact with one another in the overall application is key. For example, adhesives can serve three purposes: cover and protect, bond to a device or bond two substrates together.

Adhering to skin

Adhering components

Adhering to components to skin

If you are sticking to skin, a clear understanding of the finished device application is the first step in narrowing down the adhesive requirements.

2. How long will the device be worn?

Wear time is critical in determining adhesive requirements of the finished device. Adhesives that stay in place over long periods, two weeks or more, have different properties and chemistries than those that are meant for shorter wear times.

The adhesive strength should match that of the product's required wear time. A strong bonding adhesive for short-term wear could result in unnecessary pain or discomfort upon removal. The ideal choice will stay in place during application and then be easily removed when finished.

Reapplication of the same device or a replacement device adhering to the skin on the same site repeatedly is another factor to keep in mind when considering wear time. When not planned for, either instance can result in skin damage, especially for fragile skin. An example would be an ostomy device which is changed and reapplied every few days. Historically, hydrocolloid adhesives have been used due to their gentle adhesion and hydrophilic properties. Gentle to skin adhesives are a requirement for this type of application, and silicone adhesives are well-suited for repeat applications.

3. Who will wear it?

It is important to determine who will be wearing your device. Children and elderly or those with medical conditions may have more fragile skin than someone who is a healthy young to middle age adult. If your device will be worn over the entire population, you might want to consider developing an adhesive portfolio targeting a range of adhesion levels to suit all end user needs. A device that is specifically intended for use on someone who is elderly or an infant should be designed with the requirements for fragile skin. Also consider the health and condition of the wearer's skin, and if the device is for a specific medical condition, how this condition may affect skin.

4. Where will it be worn?

The skin on your forearm or stomach is very different in strength and elasticity compared to skin on your knuckles or eyelids. Every inch of skin has its own stretchiness and strength designed especially for its position on the body. Consider the intended location on the body which the device will be worn.

Gentle to skin silicone adhesives are advised when adhering to sensitive areas of the body such as the face, around the eyes and neck areas.

Another consideration is the contour of the body where the device will be worn. Does the patch need to move and flex, such as on the elbows, knees, face or hands? Adhesives, backings and device components made with materials that move and give with the body during use will improve performance.

5. What is the end user's activity level?

The activity level of the end user is an important consideration in adhesive selection. The adhesion requirements for a sedentary

Gentle	*Infant*	*Face*	0-3 Days
Moderate	*Child*	*Head*	3-7 Days
High-Tack	*Adult*	*Body*	7-14 Days

application, such as a sleep or snoring device, are inherently low-activity and may not require the same adhesion level as that of an active user, such as an athlete. Environmental influences, such as increased movement, sweating and climate conditions, should also be considered.

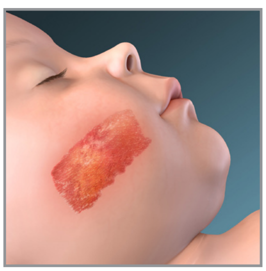
See chart on previous page that shows the adhesive strength decision criteria for the above listed key application considerations.

The Importance of Keeping Fragile Skin Safe in Adhesive Selection

The adhesive choice should be reflective of the end use application. Inappropriate adhesive choices can result in skin damage, referred to as medical adhesive-related skin injuries, or MARSI.

Skin stripping, skin tear and tension blisters occur when layers of the epidermis are removed.

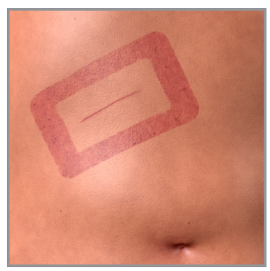
MARSI - Potential Patient Safety Concerns



Skin stripping

Tension injury or blister

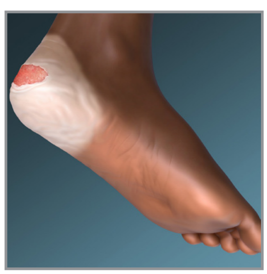
Allergic contract dermatitis



Irritant contact dermatitis

Folliculitis

Skin tear



Maceration

A tension blister can occur when a bandage is stretched upon application and further skin damage and pain.

Many of these injuries can be prevented by proper choice of adhesive, application and removal of the device. But once a patient experiences pain, they may not want to use their device again or recommend it to others, so make sure you consider the peel force to pain correlation.

Other Items to Consider in Device Design

Biocompatibility

Medical devices that encounter the body will need to be shown safe for use and will not harm the end user. For example, Reference ISO-10993-1 Biological Evaluation of Medical Devices to determine what testing is needed to show your device and the materials used in the device are safe for use on skin.

Application and Removal

How will the device be applied and removed after use? Proper application and removal techniques can affect the device function, wear time, comfort and safety.

Compatibility of Materials

Materials used in the construction of the device need to be compatible with one another to avoid cross contamination or changes in their physical and chemical properties over the life of the product.

Sterilization

Will the finished device require sterilization? Various materials may be affected by sterilization and the method of sterilization used, such as high heat and humidity exposure during autoclave or irradiation used in gamma sterilization.

Conclusion

Designing a wearable device for skin has many benefits that allow for ease-of-use and flexibility in an evolving market of point-of-care diagnostic, monitoring and treatment, and in the health and personal care-related industries. There are many challenges, as well, especially when designing for use on fragile skin.

Choosing the right adhesive for the application is key to the device's success during use. There is nothing more devastating than designing the perfect device only to find out it fails on application to the skin.

Silicone adhesives are the gentlest for fragile skin application, and their use should be considered as part of the overall device design. Early identification of adhesive requirements is key to success along with an understanding of the end user skin type and key design considerations in application, such as who, where, how long, etc.

Hopefully this guide will serve as an aid in the development of new and novel life-changing devices, as well as help prevent a few common pitfalls associated with the development of a wearable device along the way.

References:

[1] U. Blume Peytavi, Fragility of epidermis in newborns, children and adolescents. Volume 30, Issue 9, Journal of the European Academy of Dermatology and Venereology pages: 1634-1634. First Published online: August 19, 2016.Fragile Skin Classification, Physiological Fragile Skin, Skin and skin barrier in newborns and infants, paragraph 1 &2.

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[2] M.F. Galliano , C. Rouvrais , S. Bessou Touya , H. Duplan , N. Castex Rizzi , V. Mengeaud , C. Carrasco , C. Coutanceau and B. Guiraud. Title: Fragility of epidermis in newborns, children and adolescents. Volume 30, Issue 9, Journal of the European Academy of Dermatology and Venereology pages: 1634-1634. First Published online: August 19, 2016. Section: The development of cellular, tissue and clinical models to mimic fragile skin and an exploratory clinical evaluation of preparations to protect and repair fragile skin. Introduction paragraph 4.

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