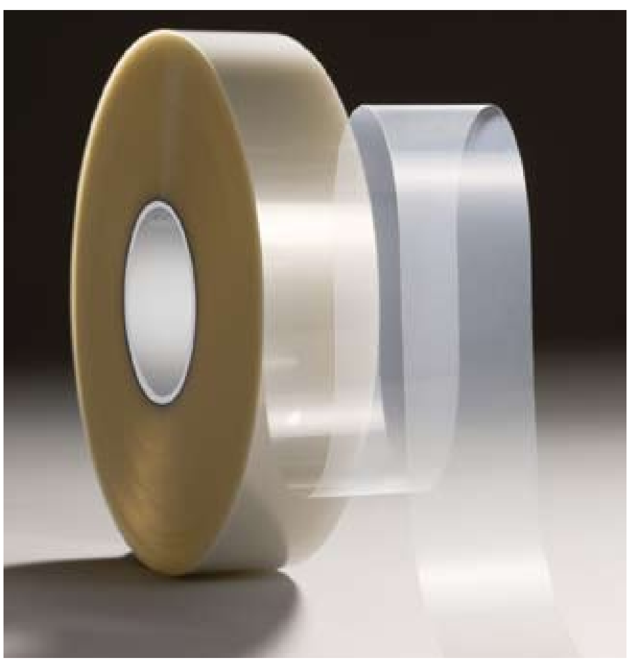
Adhesives: Managing the Skin/Device Interface

Medical adhesives are often relied upon to provide the critical linkage between the body and a medical device. To effectively interface the two, adhesives are called upon to manage a host of factors at play at the skin/device interface, such as moisture and movement, and also control the environment with respect to things like microbial flora, odor, or skin hydration.



Skin-contacting adhesive systems interact with the skin over a spectrum of length scales—from forming an intimate bond with the skin through conforming to complex curvatures of the body.

Approximate Length Scale	Skin Property or Process	Interaction with Adhesive
1 µm-10 µm	Keratinocyte desquamation	• Adhesive deadening by surface contamination • Skin stripping after repeated application and removal
	Bacterial flora	• Barrier against exogenous pathogens • Occluded skin promotes endogenous proliferation
10 µm-1 mm	Surface Roughness: Typical Height Variations 50-150 µm[a]	Adhesive flow into the microstructure needed for good bond formation and good sealing
	Surface Energy: Typically non-polar, approximately 30 dynes/cm	Wet-out on skin promotes good adhesive bond (wettability variable, depending on adhesive chemistry)
1 mm-10 cm	Surface Contours	Attachment to a movable and/or contoured surface requires conformability (consider bending resistance, tensile strength, elasticity)
	Passive moisture production (e.g. transepidermal diffusion)	Moisture buildup leading to maceration of the skin or adhesive failure
	Active moisture production (e.g. perspiration, exudation)	• Moisture buildup leading to maceration of the skin or adhesive failure • Sequestration of skin irritants in the adhesive matrix

The interactions between adhesive systems and living skin take place across a spectrum of length scales ranging from the scale of microbes living on the skin all the way through to the scale of conformability around complex body shapes or moving joints. Here, some of the key interactions between skin and adhesive across that spectrum are highlighted.

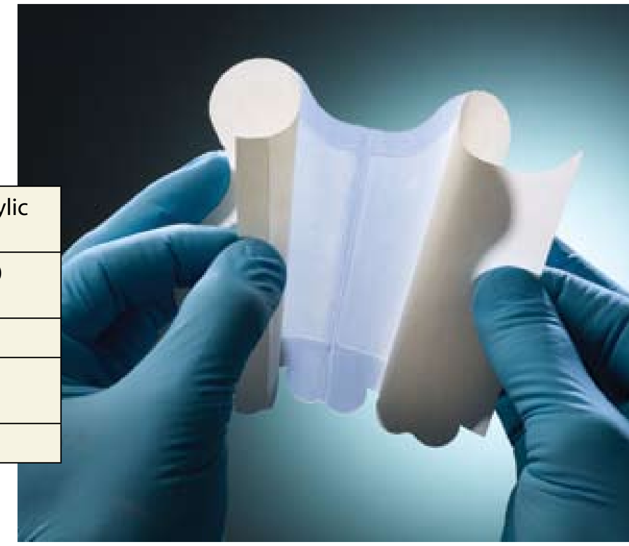
By Neal Carty, Ph.D., Research Associate, Vancive Medical Technologies

The use of pressure-sensitive adhesives to affix medical devices to the skin is ubiquitous throughout all sectors of healthcare. Some devices, like ECG electrodes, may only remain attached for short periods of time, whereas, on the other end of the spectrum, ostomy appliances may be continuously removed and reapplied to a patient's skin for many years. No matter what the application or the duration of wear, the adhesive plays a crucial role in the therapy's success because it is the material making the crucial connection between the biological (patient) and the non-biological (device). State-of-the-art medical adhesives go beyond the obvious function of bonding the device to the skin and offer sophisticated features to manage a host of factors at play at the skin/device interface.

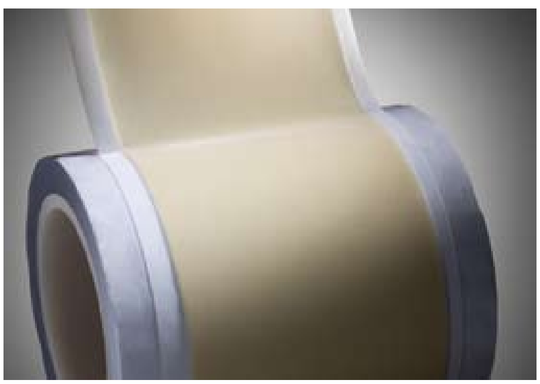
Human skin is a complex, variable, and dynamic surface, and it can be a challenging substrate to contend with when engineering a medical adhesive system. A viscoelastic material formed into a topographically complex surface, it is characterized on the microscopic level by a network of furrows, wrinkles, and pores, and at the macroscopic level, by the contoured, moving surfaces that make up the shape of the body. As a living organ, the skin is constantly responding to its environment as it adaptively exchanges heat and moisture with its surroundings: typical rates of water loss through passive transepidermal diffusion may range between 10 and 100 g/m^2-hr depending on the anatomical location, and perspiration can be significantly more. However, the skin itself is a non-polar material supplied by a steady stream of oil in the form of sebum, thus creating a surface environment that is simultaneously both hydrophobic and

	Thin Absorbent Skin Adhesive	Typical Hydrocolloid	Typical Acrylic
Fluid Handling Capacity [g/m²-day]	2410	2,000-6,000	1,000-2,000
MVTR Component	61%	10-25%	100%
Absorption Component	39%	75-90%	0
Thickness [µm]	100	300-1,500	40-100

Properties of Vancive's Thin Absorbent Skin Adhesive compared with typical ranges for traditional hydrocolloid or acrylic adhesive products.



New adhesive technologies are combining multiple interface-management properties into one system. In this case, the adhesive is thin, conformable, and absorptive, but also capable of neutralizing biogenic odors.



Hydrocolloid adhesives are able to manage fluids at the skin/device interface, whether by absorption or by forming a high-integrity seal against the skin.

water-rich. Within this ecosystem, the cycle of epidermal cell regeneration coexists with a resident bacterial microflora of between 10^1 and 10^3 colony-forming units per cm² on dry skin, such as the volar forearm, or as high as 10^6 per cm² on oily skin.[b]

Modern medical adhesives usually offer some degree of moisture management capability. Moisture management can be described in two components–moisture vapor transmission and absorption, which together add up the material's total fluid handling capacity. Moisture vapor transmission is important because occlusive conditions can promote bacterial proliferation and elevate skin hydration to the point of maceration, leading to skin breakdown or adhesive failure, or creating an increased propensity for skin tears upon adhesive removal. Together with the right choice of carrier materials, the wide array of monomer building blocks available offers acrylic adhesives a great deal of flexibility for building in high moisture vapor transmission rates to maintain breathability without the need for perforations.[c]

Hydrocolloid adhesives offer superior performance in applications where absorption is critical, specifically those situations where more significant quantities of liquid are encountered. For example, adhesives used to attach ostomy appliances may come into contact with effluent during the course of wear, and the adhesive's absorptive power sequesters the fluid and protects the skin from contact with those irritating substances. In that example, sealing the device to the skin is as important as the adhesive's absorption; moldable hydrocolloids are designed to offer enhanced flow properties and create a high integrity seal around the periphery of the flange.

Conventional adhesives generally offer an "either-or" tradeoff between breathability and absorptive power, but a new class of adhesive recently developed by Vancive Medical Technologies (www.vancive.averydennison.com) combines both properties into one adhesive system. In the examples offered previously, acrylic adhesives offer breathability, but no absorptive power and hydrocolloids' fluid handling capacities are heavily weighted towards absorption with limited breathability. Vancive's Thin Absorbent Skin Adhesive performs like a hybrid of the two, offering high fluid handling capacity that is more balanced between breathability and absorption than typical hydrocolloids or acrylics, bringing with it special advantages for products like postoperative dressings, direct-contact wound dressings, or ostomy flanges where thin, conformable, and/or transparent adhesive constructions are advantageous but good moisture handling is also required.

Adhesives incorporating active ingredients can offer a variety of other secondary benefits beyond moisture management, including odor control, moisturizing, and microbial management. Hydrocolloid adhesives have been formulated to include cyclodextrins, eliminating biogenic odors that can sometimes be associated with chronic wounds, or humectants to promote proper moisture levels conducive to healing. Acrylic adhesives have also been designed to manage the skin's microbial population. Antiseptic preparations, such as povidone iodine or alcohol wipes, can reduce but not completely eliminate the skin's resident bacterial population, so a gradual increase in microbial load underneath an adhesive film is inevitable given time, particularly under occlusive conditions. Another proprietary technology developed by Vancive provides an adhesive impregnated with chlorhexidine gluconate, a broad-spectrum antimicrobial agent. Laboratory studies have demonstrated significant antimicrobial efficacy across a broad range of bacteria and yeast commonly found in catheter-related blood stream infections.

Medical device designers have come to expect skin-contact adhesives to do far more than their obvious function, which is to create a reliable bond between the device and a huge diversity of human skin types. Secondary performance attributes, like moisture management, are often just as critical to the device's success, particularly when it comes to longer-term wear applications. Ultimately, the adhesive material brokers the interface between device and patient, so medical adhesive products must meet not only the necessary performance requirements but also satisfy biocompatibility, sterilizability, and regulatory requirements, and be manufactured under a robust quality system.

References

[a] Makki and Agache J. Soc. Cosmet. Chem. 35, 311-325 (1984).
[b] Bojar, R. A.; Holland, K. T. "Review: The human cutaneous microflora and factors controlling colonization." World J. Microb. Biot. 2002, 18, 889-903.
[c] Holguin and Koch US6558790B Water vapor-permeable, pressure sensitive adhesives 2003.