Biological factors influencing the adhesion of medical tapes

Susan M. Anasiewicz

The dominant reason for the broad acceptance of acrylic adhesives has been their claim for having a relatively low capacity to induce skin hypersensitivity.

Medical pressure-sensitive tapes are widely used for various hospital, first aid, health care, and athletic protection purposes. Dating from the mid-19th century, hospital tape is the oldest pressure-sensitive application. The entire pressure-sensitive adhesive industry has grown from this use (*1*).

Formerly, natural rubber-based adhesives were most commonly used for hospital tapes. A shortage of natural rubber during World War II caused an evaluation of other polymers for pressure-sensitive adhesives. Polyisoprene, polyisobutylene, copolymers of styrene, ethylene-vinyl acetate, and other synthetic elastomers have been used to replace the natural rubber. In the early 1960s, polyacrylates and polyvinyl ethers were introduced as hospital tapes, examples of which are shown in **Fig. 1**.

Adhesion concepts

The function of any adhesive is to bond two surfaces together. The requirements which the final bond must meet must be predetermined so that the proper choice of an adhesive can be made. The most critical requirements for adhesives are the extremes of heat and cold and the extremes of moisture and dryness.

Many theories have been proposed to explain the process of adhesion. Present theory explains adhesion as the result of a specific attraction caused by chemical, physical, and electrical forces. In general, there are three methods by which adhesive bonds might be affected: (a) physical or mechanical bonds, (b) secondary chemical bonds, and (c) primary, ionic, or covalent bonds.

Physical or mechanical bonds are those formed by the inclusion of a material within the crevices of a substrate. Materials which could function well by this kind of mechanism would be highly fluid products. The physical factors in adhesion include (a) closeness of contact, (b) surface area, and (c) stress conditions. The character of the surface of the adherend and the physical state of the adhesive must be such that the molecules of the two materials are brought close enough in contact for the molecular forces to become operative. The surface area must be large enough to allow the adherend molecules to "react" with the adhesive molecules. Conditions for combining the adhesive and the surface must be closely controlled to minimize stress. Bond strengths depend on the inherent mechanical properties of the specific adhesive material.

Secondary chemical bonds are those attributed to forces such as hydrogen bonding or van der Waals' attraction. These are secondary valence forces, some of which depend on the chemical nature of the two adhering molecules. A universal component of the van der Waals' forces is the London Dispersion Force, which acts between molecules regardless of their chemical characteristics. These forces are of sufficient magnitude to contribute to the strength of some adhesive joints.

Primary bonds are obtained by the chemical reaction of an adhesive material with the substrate. The limiting strength of such bonds might approach the high inherent strengths of interatomic bonds such as carbon–carbon and carbon–hydrogen bonds.

Other factors that affect adhesion include:

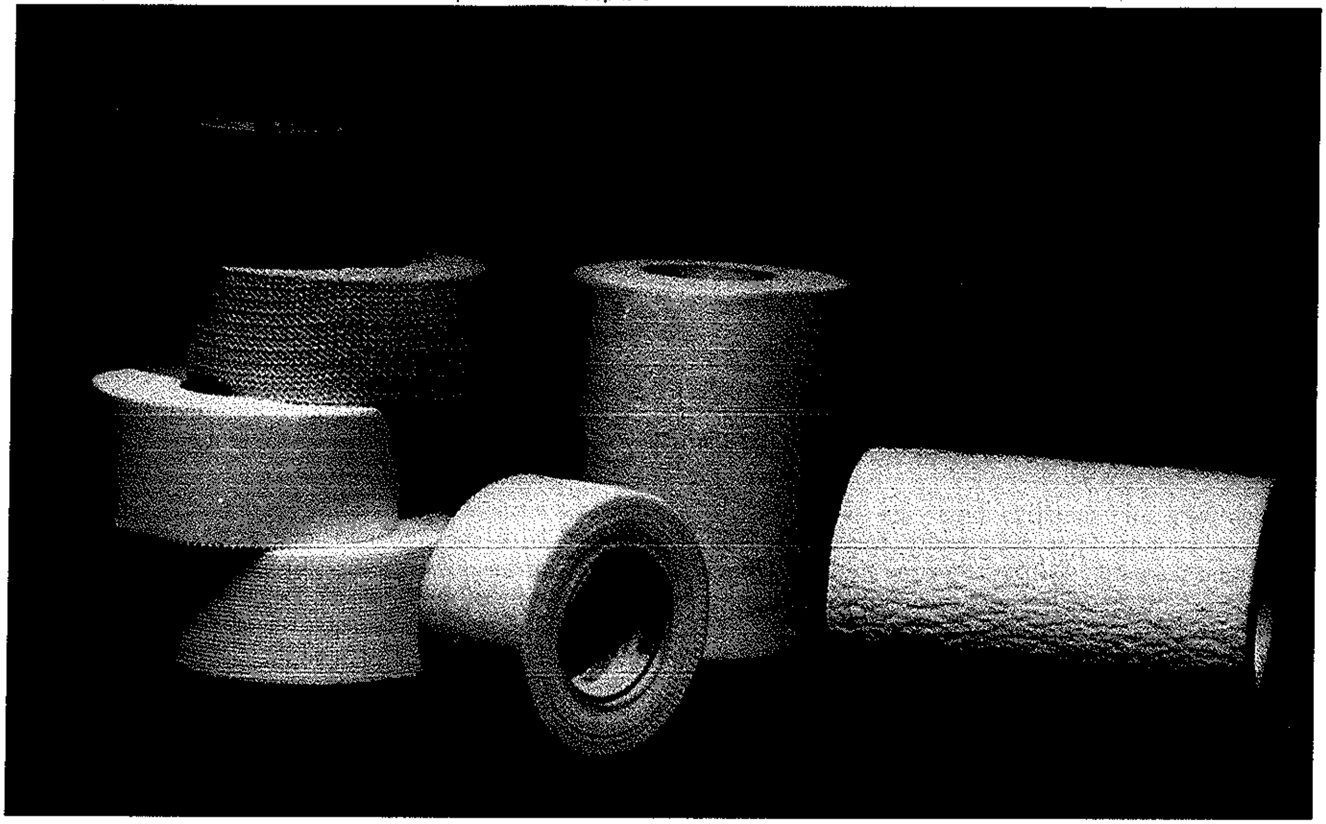
1. Molecular weight
2. Molecular weight distribution
3. Plasticizers
4. Tack temperature
5. Absorbed material
6. Porosity.

Low-molecular-weight materials generally have low cohesive strength. High-molecular-weight materials generally have low bond strengths because the adhesive does not flow sufficiently to make good contact with the surface or because the adhesive may become too rigid to relieve stresses developed during setting. Polymers of intermediate molecular weight generally provide the highest bond strengths. Adhesives which contain a high ratio of low-molecular-weight fractions to high-molecular-weight fractions in a polymer tend to act as plasticizers. Polymers where molecular weight distribution follows the binomial distribution curve generally make the best adhesives.

The addition of plasticizers to polymeric compounds increases flow characteristics while decreasing cohesive strength. By proper choice of plasticizer, it is often possible

Anasiewicz is senior research chemist, Johnson & Johnson Health Care Co., North Brunswick, N.J. 08902.

1. Examples of pressure-sensitive adhesive tapes used in hospitals



to increase or decrease the adhesion of a specific adhesion system.

The tack temperature is related to molecular weight and flow characteristics. It is a measure of the state in which the material flows readily. An adhesive with low tack temperature will have low cohesive strength. One with high tack temperature will not have the required flow characteristics.

The presence of absorbed gases, oil, water, or other material on the surface of the adherend is often the cause of inconsistent sealing or bonding. Special cleaning and handling techniques may be required to obtain reproducible results.

The porosity of a surface affects bonding in many ways. If the adhesive flows into the pores and solidifies, an increase in adhesion is affected, caused by a greater area of contact. Bond strength may be reduced, however, because:

1. A porous surface is difficult to clean.
2. Porous surfaces are often not sound. (Failure in cohesion rather than in adhesion may be found.)
3. It is more difficult for the adhesive to set the surface.
4. Gases may be trapped in the pores, limiting contact between adhesive and adherend.

Several excellent treatises on adhesion have been published in the past, but the emphasis has been on types of adhesives commonly used to bond surfaces of paper, wood, metal, plastics, etc. Although a general physical approach to contact phenomena has been previously discussed, a specific detailed biophysical analysis of adhesion involving the heterogenous dynamic periphery of living tissue is nearly nonexistent. The main difficulty is that current experimental techniques give us estimates of variable reliability of average parameters, and these averages are hardly sufficient for the detailed, unequivocal analysis of even "simple" nonliving systems and are grossly inadequate for living tissue.

Biological factors in adhesion

In all vertebrates, the skin consists of two major layers. The richly cellular, relatively thin outer layer, derived from the embryonic ectoderm, is called the "epidermis." The thicker and tougher inner part, of mesodermal origin, is largely composed of fibrous connective tissue and is called the "dermis," "cutis," or "corium."

The skin of man, from the surface to the point where the dermis merges with the usually fatty subcutaneous tissue layers, varies in thickness from less than 1 mm on the eyelids to 3 mm or more in the region between the shoulder blades and on the palms and soles. It is elastic and presents a smooth, soft, pliable surface broken by intersecting lines, folds, ridges, and tiny pores. The average thickness of the epidermis is only about 0.1 mm. On the palms and soles or where the skin has been subjected to rubbing or pressure, the epidermis may be 10–15 times thicker.

The most superficial layer of the epidermis, the stratum corneum, consists of 10–20 layers of flat, dead, dry, keratinized cells, which adhere to one another tightly except nearest the surface, where they are continually shed as microscopic flakes. The prevalent chemical constituents in skin are amino acids having various hydroxyl and carboxylic acid groups. Human skin is extremely variable as a consequence of its structure and activity, having a layer of lipids that are obtained from endogenous sources (including cornification of the epidermis), exogenous sources, and sebaceous glands (*2, 3*).

Skin irritation

There are several causes of skin irritation. The tape construction, backing, and adhesive contribute to the degree of irritation. Mechanical irritation may be caused by applying a stiff tape over the skin, which is frequently flexed. The skin is irritated by the continuous pull of the adhesive. Usually, however, the mechanical irritation is caused by the tape removal. It can be temporary, caused by vasodilation in which no damage of the skin occures, or it can be of a longer duration, caused by stripping the outer layer of skin. This latter case is the most common cause of skin irritation by pressure-sensitive adhesive tapes.

Changes in the cohesion of horny layer cells produced by wearing tape may be manifested by reactions similar to an allergic response. Tapes can interfere with the normal physiological activity of the skin. The major effect produced by wearing adhesive tapes relates to environmentally induced alterations that are imposed on the stratum corneum cells. Hydrated cells under a tape with a low rate of moisture vapor transmission have grossly altered physical properties compared to uncovered skin.

Occlusion is an environmental alteration which overhydrates, mascerates, and softens the outer layers of skin as a result of the accumulation of fluid. These outer layers at normal environmental humidities are dry and strong, but when hydrated, they become weak and are easily damaged. When a tape is removed, the cohesion and mechanical strength of these cells determines whether they will remain in place or be removed with the tape.

Skin weakened by maceration can split inside when the tape is removed. Upon occlusive tape removal, variable planes of separation within the skin develop. Separation occurs not at the skin-adhesive interface but deeper in the tissue, resulting in irregular delamination of the stratum corneum. The adhesion between the tape adhesive and the outermost layers of skin is far greater than the internal strength of the stratum corneum. Irregular, deep fractures at these layers occur as the tape is removed, leaving a large amount of stratum corneum cells on the tape. This removal often produces skin damage which becomes exaggerated when fresh tape is reapplied over the same area.

The subsequent redness that develops can often be confused with chemical irritation or an "allergic" response. When a porous tape is removed, the planes of separation develop near the surface of the stratum corneum, in the region of the naturally desquamating cells. Thus, only small amounts of stratum corneum are lost during tape removal. This advantage allows for repeated use of tape over the same site with minimal damage to the skin (*4*).

Overhydrated skin is also more easily penetrated by chemical irritants and, therefore, is more susceptible to irritation of this type. Chemical irritation is caused by the diffusion of chemical irritants, present in either the adhesive or the backing, into the skin tissues. Sometimes the area beneath an occlusive tape can become completely anhydrous because of the blockage of the openings of sweat ducts. The interface between the dehyrated skin and the tape becomes suitable for the growth and multiplication of bacterial flora, resulting in infection.

Allergic irritation is caused by some tape ingredient to which an individual is sensitized. This type of irritation is not as common as generally claimed. The allergic reaction is easily distinguishable from the mechanical one; it spreads beyond the area over which the tape was applied, while the mechanical irritation is confined to the skin that was covered by the tape (*5*).

The dominant reason for the broad acceptance of acrylic adhesives has been the claim for hypoallergenicity. Rubber-based, pressure-sensitive adhesives require a large number of components, including natural or synthetic rubber, resin, tackifiers, antioxidants, plasticizers, fillers, and pigments, many of which are derived from plant sources. Consequently, there is a potential for introducing irritant and sensitizing agents.

Single-component acrylic adhesives with hydrophilic properties and high rates of moisture vapor transmission can absorb moisture and allow its passage, resulting in a low potential for traumatic response. With these pressure-sensitive adhesives, the moisture content of the horny cell layers remains relatively normal, and its capacity as a dry-strength tissue is retained. A nonocclusive adhesive may not necessarily be porous; it can also transmit moisture at a sufficiently high rate by absorption and diffusion.

The topography or surface roughness of the skin is important because it influences the interactions across the interface. Little is known about the effect of roughness on the surface properties of skin. Since we are dealing with a highly pliant substrate, the roughness will vary with the imposed tension of the skin. Tension is imposed by flexing and unflexing the various joints. This flexing affects the interface in two ways: it changes the surface rugosity and imposes stresses at the interface, specifically on the adhesive. Failure will result if the adhesive does not deform sufficiently to relieve these stresses.

An adhesive intended for application over skin must be fairly soft with a low modulus of elasticity at low elongation. Adhesives with high elastic moduli disbond easier on continuous flexing and are more liable to cause mechanical skin irritation. These high-modulus adhesives with good creep resistance are generally used for industrial tape applications.

A good hospital tape has an adhesive that exhibits cohesive failure at low peel rate, ensuring that the adhesive will fail only when its maximum elongation is reached and that it will not easily disbond in use. At higher peel rates, these tapes show adhesive failure and therefore will come off cleanly when removed. Soft adhesives with low moduli of elasticity exhibit low cohesive strength and would split on removal, leaving a residue on the skin.

In addition to stratum corneum cohesion, a number of other biological variables may have an influence on adhesion. Transepidermal water loss, or the water of diffusion through the epidermis under non-sweating conditions (sometimes called "insensible perspiration"), is fairly constant for a given person and site at a given ambient temperature. Higher transepidermal water loss indicates slightly thinner, more permeable stratum corneum and/or slightly higher skin surface temperature. The skin elastic response, or the elasticity of the dermis which lies beneath the stratum corneum, may also have an effect on skin adhesion. The mechanical properties of this component determine "firm" or "flabby" characteristics. It was conjectured that body movements associated with an individual's activities would be more readily transmitted as stress changes at the interface of the skin and adhesive in individuals with "firm" skin as opposed to those with "flabby" skin. Skin surface lipids, sweat production, and physical activity also play important roles in adhesion to skin.

Several methods were developed to study the details of the interaction at the interface between the skin and the adhesive. Wear-testing subjects were characterized as "stickers" or "nonstickers" on the basis of measurements of rank adhesion. These same subjects were then measured for transepidermal water loss, skin surface topography, viscoelastic properties of skin, and eccrine gland density, or sebaceous secretion activity.

Measurements were made using an Alexander Cook Device, which is an *in-vivo* mechanical tester that measures the viscoelastic properties of skin at deformations less than 20%. In this case, the stratum corneum is assumed to have a minor effect, and the viscoelastic response is primarily caused by the underlying dermis.

Measurements were also made using an Acoustic Spectrometer with a specially designed transducer that measures viscoelastic properties at deformations less than 1%. In this particular case, it is assumed that the response of the stratum corneum is measured without disturbing the underlying dermis. A method was used for determining the quantitative sweat production by means of Bromophenol Blue in an alkaline medium of powdered sodium carbonate, gum Tragacanth, and starch. Lipid production was measured by using CELGARD™ brand porous polypropylene backing coated with an acrylic adhesive.

No significant differences were found between the mean values for high- and low-adhesion subjects, either in removal force, measuring the cohesive strength of the skin, or in elongation at break, measuring the elasticity of the skin. From analysis of lifestyles and observations of work functions, it appears that adhesion to skin of pressure-sensitive tapes is dominated by the mechanical strains during wear and sweating, especially if perspiration occurs within a short period after the tape is applied. In other words, "stickers" exhibited high lipid output and low sweat production, while "nonstickers" had low lipid output and high sweat production. There were no significant differences in skin mechanical properties between "stickers" and "nonstickers."

Summary

The characteristics of a good medical tape include the absence of skin-irritating ingredients, a high water vapor transmission rate to decrease occlusivity, a cohesive strength high enough to allow the adhesive to be cleanly removed from the skin, rheological properties to accommodate skin movement without excessive mechanical skin irritation, and good water resistance. Future developments in medical tapes are likely to require wet stick and high adhesion, with low removal forces.

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Received for review May 17, 1988.

Accepted June 1, 1988.

Presented at the 1988 Polymers, Laminations and Coatings Conference.