Adhesives Research®

IMPORTANCE OF ADHESIVE SELECTION IN WEARABLE DEVICES FOR DRUG DELIVERY SYSTEMS

In this article, Gozde Karabiyik, PhD, Product Development Scientist, Adhesives Research, highlights the crucial role that the adhesive plays in the success of a wearable injection device, describes in detail some of the challenges relating to skin adhesives – both general and specific to their application in wearable injectors – and provides advice and solutions to help with successful adhesive selection.

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UNDERSTANDING ADHESIVE CHALLENGES WITH WEARABLE DEVICES

The development of wearable devices is rapidly increasing in various areas of healthcare and wellness. Medical devices are advancing from portable equipment to small devices that can be worn on the body for several days of continuous physiological monitoring and delivery of certain biologics. Wearable drug delivery devices have become very important in the delivery of insulin and other large compounds to subcutaneous tissues. These wearable devices utilise skin adhesives to secure bonding to skin to deliver target therapeutic doses reliably.

When developing an effective and robust wearable drug delivery system, it is important to understand the factors influencing adhesion of the device to skin (see Figure 1). During wear, the adhesive and skin bond of a device are constantly challenged by external factors which cause the edges of the adhesive to lift off of the skin, making the device vulnerable to premature fall off. Factors that cause this type of edge lifting include: friction (created from clothing, moving and stretching due to physical activity), as well as moisture exposure, and varying skin types. In wearable device applications such as patch pumps, infusion sets and continuous glucose monitoring devices further challenges arise from the weight of a device or limited moisture vapour transmission from under the device. Differences in skin surface energy and stretching resulting from age, race, and patient health also contribute to variation in adhesion levels. Likewise, placement of a device on different body locations affects wear performance.

UNIQUE CHALLENGES FOR SKIN ATTACHMENT

The performance of a wearable drug delivery device depends on how reliable and reproducible the attachment is on the body for the targeted wear time. It is important to consider the physiology of the skin to develop skin-friendly adhesive

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platforms. Wearable device applications present unique adhesion challenges due to the skin's complex structure that changes based on each individual's age, gender, race, and diet. Skin is a living and breathing substrate; therefore, numerous properties of skin affect wear performance, making it challenging to design a skin adhesive that performs the same for every patient within a large population.

Skin has an irregular surface with hair, pores and wrinkles. As a result, an adhesive should have good balance of viscoelastic properties to be able to flow on the skin surface for efficient bonding and remove cleanly with no residue. In addition, skin has a low surface energy for which the adhesive must replicate an equivalent or a lower surface tension to achieve sufficient bond to skin surface. The surface energy is variable depending on the area of the body. Clean, dry skin has a lower surface energy than the forehead, which is typically oilier than the rest of the body. Another critical factor is the placement of the device on the body as it plays an important role due to differences in curving and stretching of skin.

For example, placing a device on the abdomen (see Figure 2) will create different stress on the adhesive compared to the shoulder (Figure 3) or arm during daily activities. In some cases, such as patch pump users, patients prefer to place the device on different parts of the body and expect the same wear performance.

Moreover, the activity levels for specific patients can be dynamic where the user needs to carry on daily activities including exercise and showering. Environmental factors such as relative humidity and temperature depending on seasonal changes can also have an impact on adhesion to skin. Therefore, it is critical to understand the skin type, activity level of the target population, location on the body and environmental conditions related to a specific application.

ADHESIVE REQUIREMENTS: BIOCOMPATIBILITY & BREATHABILITY

The application of pressure-sensitive adhesives (PSAs) in skin-contact products requires several important features that predetermine their composition, structure, and processability. These features are connected with the biological properties of skin and its nature as a substrate.

Figure 1: Factors to consider for adhesives used in wearable devices.

Figure 2: Adhesives Research's skin-friendly wearable adhesives for abdomen placement.

Figure 3: Adhesives Research's skin-friendly adhesives for shoulder placement.

Adhesive biocompatibility is a significant concern in any skin adhesive application. Medical devices may be applied to skin that is compromised due to acute, chronic, or systemic conditions; therefore, it is important that no component of the adhesive aggravates the skin further. Skin adhesives should be formulated carefully to provide a biocompatible adhesive system to prevent any adverse skin reaction. There should be no toxic components that can be absorbed through broken or compromised skin, but there should also be no residual components that could cause an allergic sensitisation response or an acute chemical irritation. Presence of any residual unreacted free monomers, stabilisers, cross-linking agents, residues from initiators, surfactants, and processing aids could potentially cause skin irritation and sensitisation.

Skin breathability through the adhesive is essential to prevent maceration and irritation during wear due to lack of water transport from the skin. In some applications, maintaining a certain hydration level at skin and adhesive interface is critical for enhancing drug flux. In this case, the skin becomes weak due to maceration and it can result in potential tearing and pain during device removal. Moreover, it is also prone to infection. Skin breathability affects device wear ability, depending on the moisture vapour transmission rate (MVTR) of the device design as well as the adhesive construction. Breathability of skin adhesives can be increased via adhesive and substrate selection, lowering adhesive coat weight, and zone or pattern coating. Adhesive tapes with high MVTRs prevent accumulation of moisture at the skin/adhesive interface which typically causes premature device fall off.

Wear performance of an adhesive tape also depends on device design, i.e. size and shape of the device and how it fits body contour. Variations in device designs and skin property of the target population result in the need for customisation of skin adhesives specific to each application. In terms of device design, height of the device is critical as the profile of the device influences probability of getting caught by clothing. Devices that are bulky and heavy create bonding challenges. Moreover, device weight exerts shear force yielding failures, therefore selection of the adhesive at correct levels of aggressiveness to tolerate device load is important. In addition to size and weight of the device, the area of the device that covers the skin adhesive influences wear performance. If the footprint of the device is the same as the skin adhesive, the breathability is limited and the moisture build-up under the device may result in delamination. If the skin adhesive layer

is extending around the perimeter of the device, the wear performance is enhanced by breathability of the additional adhesive.

A good balance of adhesive and cohesive properties provides sufficient bonding to the skin and prevents sliding of the device while on the skin due to the forces exerted by the weight of the device. The adhesive needs to have adequate shear strength to carry the device with no creep and no residue. Cohesive strength prevents sliding of the device on skin over time and avoids formation of a black ring around the device patch. Formation of a black ring is usually encountered with adhesives that are soft and aggressive where lint and dirt adheres to the adhesive edge so when the patch is removed it leaves a black residue trace. In addition to cohesive strength, adhesives with a high level of initial tack perform better due to the need for a quick stick of the device on the skin soon after it is applied. If the adhesive requires a certain amount of dwell time on the skin to build adhesion, then the device may prematurely lift off due to its weight.

Depending on the application, the device including the adhesive may be sterilised via gamma, e-beam or EtO sterilisation. In these instances, it is important to ensure that adhesives that retain adhesive and cohesive properties upon sterilisation are utilised in device design.

In summary, it is critical to understand device design, dimensions, weight, and patch design and application duration to develop a skin adhesive specific to an application.

LOW-TRAUMA ADHESIVES FOR SHORT-TERM WEAR

There is a growing need for low-trauma adhesives to provide reliable adhesion on different skin conditions and age groups with gentle removal experience. Moreover, treatments for chronic conditions require repeated application and removal of a skin patch on a specific skin site. Adhesives Research is addressing the need for gentle and repositionable skin adhesives through the development of low-trauma adhesive (LTA) technology for gentle removal (SoftWear®). This customisable PSA platform technology maintains intimate skin contact for up to three days with painless and residue-free removal.

The SoftWear® adhesive platform is repositionable and allows a clean release from skin and hair. Silicone and non-silicone formulations are available under this adhesive platform. Unlike traditional skin adhesives, SoftWear® adhesives do not lose tack after removal from skin; therefore it can be applied to the skin and removed multiple times allowing users to reposition the devices on their skin if needed. SoftWear® adhesive has thinner product profile that provides reduced edge lift and grab to clothing. Gentle removal of this adhesive makes this adhesive platform ideal for paediatric and geriatric applications. The adhesive is formulated to release from hair and the top layer of skin cleanly with a pain index <1 on the Wong-Baker FACES® Pain Scale. For comparison purposes, a standard skin-friendly adhesive has a pain index rating of 4-5 on this scale based on internal studies. In addition, LTA formulations exhibit resistance to radiation sterilisation techniques.

SKIN-FRIENDLY ADHESIVES FOR LONG-TERM WEAR

Wearable drug delivery devices are designed for long wear times extending adhesion on skin beyond seven days. Adhesives Research has designed a tailorable biocompatible adhesive technology that provides an aggressive long-term wear (LTW) adhesive platform to secure a wearable drug device on skin for up to 14 days. This adhesive platform ensures bonding of the tape to skin with minimal edge lift during the course of wear and removes from the skin cleanly without leaving any residue. In spite of its strong adhesion on skin, LTW adhesive does not cause disruption of the stratum corneum after removal. Studies have also shown that pain experienced upon removal of the tape is tolerable and results in a pain index of <2.5 on the Wong-Baker FACES® Pain Scale. This adhesive platform provides high MVTR for breathability and good wear properties with no edge residue or cold flow. It can be further tailored to customise the wear time and adhesion levels depending on the wear duration and device design of a specific application.

CONCLUSION

It is challenging to have one adhesive that performs well across all variables. It is critical that the device is designed to understand adhesive tape behaviour and challenges with various skin types, age groups, activity levels and living environment. Adhesives Research understands the unique challenges of skin attachment due to load created from the weight of the device, the need for immediate adhesion to skin and the complex nature of skin.

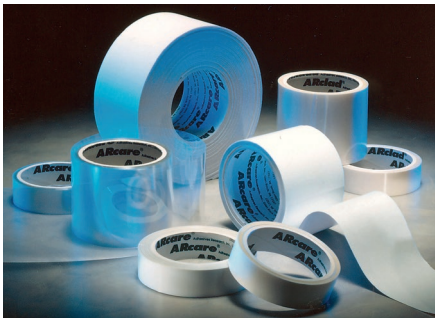

Figure 4: Adhesives Research's skin-friendly adhesives.

Consideration of physiology of the skin and device design led Adhesives Research to develop skin-friendly adhesive platforms to provide custom solutions to unmet needs of various skin attachment applications (Figure 4). Skin-friendly adhesive platforms include SoftWear® (gentle adhesives), long-term wear adhesives which are biocompatible per ISO 10993, non-cytotoxic, non-irritating or sensitising. These platforms are ideal for providing skin attachment of numerous devices such as sensors, infusion pumps, and patch pumps with various sizes, weights and application times. The adhesive platforms have been integrated in many skin adhesive products for a number of wearable device applications.

ABOUT THE AUTHOR

Gozde Karabiyik is R&D Product Development Scientist for the Medical and Pharmaceutical divisions at Adhesives Research. Since starting with Adhesives Research in 2009, Dr Karabiyik has focused on the custom development and manufacturing of adhesive technologies for diagnostics, wearable medical devices and wound care applications. In 2011, her co-authored paper won the Carl Dahlquist Award by the Pressure Sensitive Tape Council, (PSTC). Dr Karabiyik earned her PhD in Macromolecular Science and Engineering from Virginia Tech (Blacksburg, VA, US), her MSc in Materials Science and Engineering from Sabanci University (Istanbul, Turkey) and her BSc in Chemistry from Izmir Institute of Technology (Izmir, Turkey).