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Technical Paper

Skin vs. Stainless Steel Adhesion Testing for Medical Design

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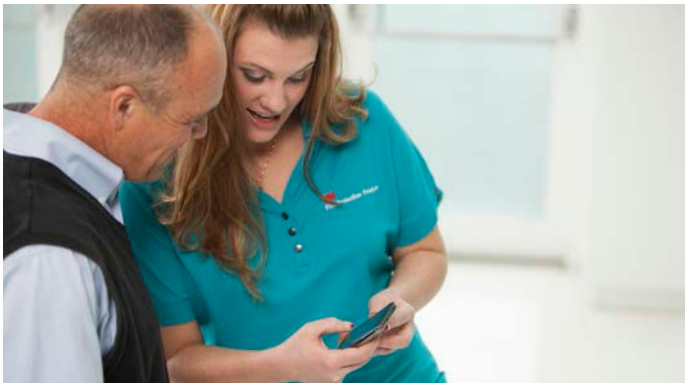
Customer: I need to attach my device to skin. Can you give me a tape that will hold the device to skin until the patient is ready to remove it? What would be the stick to skin properties for such a tape?

Manufacturer: We provide a number of tapes that are suitable for skin contact with different adhesion values as measured on stainless steel. We would be happy to supply you with some appropriate tape samples for evaluation in your application. Can you please elaborate on your application a little more?

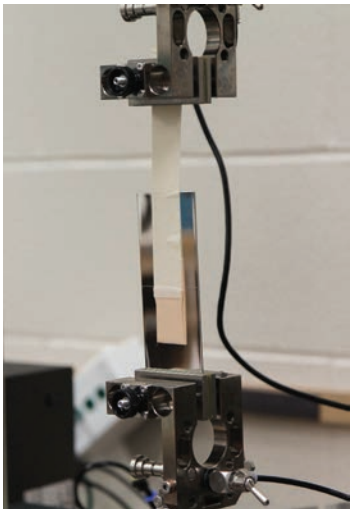
Customer: But I want to know the skin adhesion for the tape, is that the same as adhesion to steel?



And so it goes!

Although it sounds confusing, there is good reason for a manufacturer to make product and have quality control via a property that can be well controlled and measured, to make consistent product. Although the tape may be used on skin, skin adhesion is not a constant – it varies with numerous factors, some controllable and some inherent and uncontrollable. Some controllable factors that affect adhesion to skin are presence of hair, use of lotions, etc. Some uncontrollable factors are climate, age, health status, diet, race, oil production, etc.

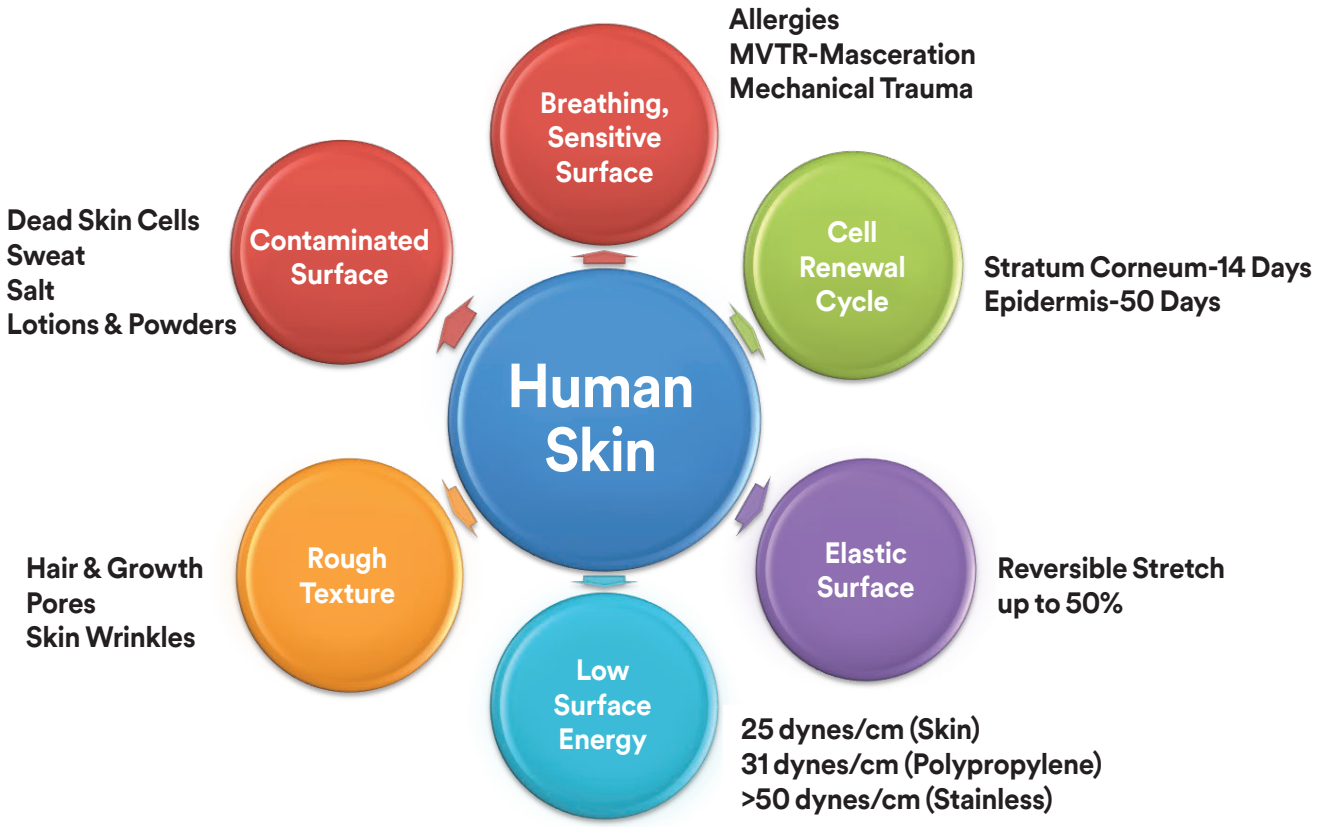
Thus skin adhesion measured on the same individual, with the same tape at different times of the year or even at different locations on the body can produce different results, making adhesion to skin too variable to make a good quality release test. On the other hand, adhesion of the same tape made at different times following the same production standards to a standardized substrate, such as bright, annealed #302 or #304 ANSI[1] stainless steel will provide a reproducible value under controlled conditions and therefore is a desirable choice as part of a quality control specification.



With medical device regulations varying around the world, ISO[2] standards and other organizations such as ASTM[3] and PSTC[4] have spent a great deal of time and effort producing guidelines and directives that allow developers to reproduce (given the right inputs, equipment and training) testing done in one location at a facility halfway around the globe – with some reliability. There may be differences due to equipment, software, calibration and the infamous operator error but if charts are adjusted to account for these differences, based on repeat testing of identical lots and consistent operator training, incoming raw materials can be tested using standardized substrates. This is not possible with human skin.

The Trouble with Skin

Many efforts have been made to find or develop a good substitute for in vivo human skin testing. Studies of substrates range from various plastics such as low density polyethylene and epoxy surfaces to high tech lab-grown skin[5]. Some will reproduce initial adhesion and are often used during early stages of medical tape development. None of the current or past material substitutes provide a standardized surface that produces data predictive of adhesion to skin over time.



Having said that, a number of factors go into an adhesion value to any substrate other than simply adhesive coating weight. There are different adhesive families such as acrylics, synthetic rubbers, silicones, etc. that may or may not provide the same initial adhesion to the selected substrate and the adhesion levels can be greatly affected by dwell time on the substrate. Other factors include the backing or carrier material the adhesive is coated on, the thickness or stiffness of the backing material, angle and speed of removal, etc. Skin and its special properties add to this already long list of factors.

Human skin is an uneven, elastic surface that is constantly renewing itself while producing sweat, oil and hair at rates that may differ greatly between individuals. The stratum corneum is littered with dead and loose skin cells and the base "surface energy" (a standardized measurement – in dynes – often used in the printing industry to assess ink adhesion levels with higher dyne levels easier to print) is as low as most polyolefin plastics. If the tape sticks too well, you run the risk of causing mechanical trauma at removal or if you choose the wrong formulation ingredients you can irritate allergen-sensitive skin. A thorough cleansing with soap and water helps prepare the surface but only for a short time. Oils and sweat combined with hair growth/regrowth and natural turnover of the surface cells every 14 days or so make adhesion to this ever changing substrate very difficult and, at this point in time, commercially impossible to duplicate for standardized testing.

Things to Consider

So what can designers and product developers do to create the best possible products, such as sensors and wound care dressings, to adhere to skin while following the medical creed to "do no harm?"

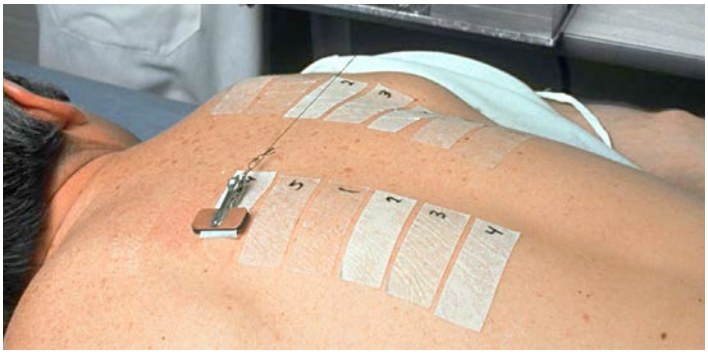
First, choose the "right" adhesive for your application. Synthetic rubber-based, acrylics, hydrocolloids, hydrogels and silicones all have good and not so good applications in the medical and retail device marketplace depending on the age range (geriatric/neonates versus healthy adult), device placement (thin skin/eye areas versus feet) and length of wear needed (one hour, one day or one week).

Adhesion to skin can be represented as a bell-shaped curve for attachment to skin – there will always be some people at both ends of the curve – on the low end there will be people that nothing seems to stick on them for very long. The opposite end of the curve are those who seem to attract adhesives and tapes adhere too well – often resulting in mechanical irritation or even stripping of the top skin layers. Dry and/or fragile skin is prone to this type of reaction and only the gentlest adhesives or the application of a skin primer/protective preparation should be considered before attaching the device.

Next, read the literature. You can still use adhesion to stainless steel or low surface energy plastics (untreated low density polyethylene, for example) to get an idea of very short term or initial adhesion to human skin. These surfaces do work as

guides - for the first hour or two of adhesion. Better yet, look for adhesion to skin testing. This type of testing uses a group of paid volunteers as test "substrates" and the results are reported as averages of removal peel strength after the tape samples have been in place – often on the back or abdomen - over a period of time.

Most formal panel studies accomplished at registered clinical test sites require a written protocol and submission of a data package that includes product safety summaries, such as ISO:10993 testing or a toxicology assessment, for approval by an In-House Review Board (IRB). The panels are typically limited to healthy adults with ages ranging from 21 to 65 – standard workforce age range. These results will give a good idea how well the tapes hold on this limited population sample at the time and place it was run – not ideal if your target patient or customer is younger, older or somehow compromised but is an improvement over plastic and steel. Athletic applications can often specify clinical panel testing that includes controlled situations that parallel actual use conditions such as swimming and aerobic exercise. Choose at least a couple of adhesive products that look as though they might possess the qualities you need and order enough samples for application training the other contingencies. Tapes need to be tested on the same group of subjects during the same period of time to truly compare "apples to apples."



Choose the body area that best duplicates or reacts similarly to the type of skin your device is targeting – the abdomen (except on a serial tanner) or inner surface of the upper arm are very good areas to check for gentle adhesion. These areas are thin, supple and may mimic fragile skin types. Try the upper back or outer surface of the arm for general use (remember to clip hair as needed to avoid extra trauma from pulling it during removal). If you are designing for an athlete, be sure to test while active – sweating does make a difference and breathability helps reduce moisture build-up!

Less breathable products may help reduce the adhesion levels if worn for more than three days which can be a positive if you need strong adhesion but the breathable version was too aggressive upon removal. That same adhesive on the breathable backing might be the right one if you have designed a seven day wear device. Always make sure the skin area is clean and dry before adhering the samples to the surface – no lotions, powders or creams which can interfere with getting a good initial bond. Simple soap and water work very well and leave little or no residue.

Conclusion

Evaluate the results, and possibly your product design, to maximize success at this stage of development. A few get it right the first time but trial and error in vivo can be viewed as a learning experience that improves your current design and builds your knowledge base for the next project.

References

[1] American National Standards Institute

[2] International Organization for Standardization

[3] ASTM International, formerly known as the American Society for Testing and Materials

[4] Pressure Sensitive Tape Council

[5] *Peel Adhesion Using An Artificial Skin As A Predictor Of Adhesion To Human Skin*, Cantor, Adam S., 3M, American Association of Pharmaceutical Scientists Annual Meeting; New Orleans; November 14-18, 1999.

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