

# INNOVATION IN MEDICAL ADHESIVES

Kiu-Yuen Tse, Ph.D., Advanced Research Specialist, 3M Corporate Research Materials Laboratory, St Paul, MN

## Abstract

Medical tapes and dressings are commonly used in hospitals to cover wounds and secure dressings or devices on patients' skin. Repeated application and removal of medical adhesives may result in trauma to skin causing severe patient discomfort as well as expensive interventions. In this paper I will describe a new silicone-based medical adhesive that was designed to be gentle to sensitive skin without sacrificing securement of dressings or light tubing. After an initial introduction into the unique challenges of skin as a substrate, I will discuss the rheological characteristics of this unique adhesive system and the methodology of how gentleness is quantified within clinical research.

## Introduction

Medical adhesives are a unique class of PSA (pressure sensitive adhesive) specially formulated and designed to adhere well to human skin. In terms of adhesion, skin is a unique and especially challenging adhered (or substrate) for PSAs. Skin is actually a living organ, the largest human organ. It is a dynamic substrate and is regenerated approximately every 14 days. <sup>(1)</sup> Skin is a low modulus material and an elastic and flexible adherend. It is a rough surface to adhere to and can be considered a highly contaminated surface with considerable and varied amount of oil, sweat, lotion, dead and living skin cells. Depending largely on the amount of oil, skin can be a low surface energy substrate, with a critical surface tension of about 24 dyne/cm. <sup>(2)</sup> Skin as an adherend is also highly variable, for example location on the body, age, gender, race, health condition and seasonal fluctuation all contribute to variation in skin adhesion. As a result of these variations, typically well-designed, IRB approved clinical studies with a large enough number of study subjects are required to study skin adhesion quantitatively.

## Medical adhesive-related skin injury (MARS)

In addition to the above, being a living organ, skin is a breathable and sensitive substrate. It is prone to mechanical and chemical irritation and potential allergic reaction. Medical adhesive-related skin injury (MARS) is a common, under-recognized and potentially under-reported complication in health care settings. <sup>(3)</sup> MARS can occur when medical adhesives are not removed from skin carefully and with proper technique. Figure 1 below shows examples of MARS. From left to right, the top row shows an example of skin stripping, where one or more layers of the stratum corneum was removed by the adhesive and can be characteristic with the skin appearing shiny. The top middle picture is an example of skin tear, where a wound was caused by shear, friction or blunt force. Top right picture is an example of contact irritant dermatitis, where a well-defined area contacted with the medical adhesive showed redness resulting from chemical irritation. Bottom left picture shows skin irritation caused by adhesive. The bottom middle picture is an example of tension blister, caused often times by incorrect application of medical tape/dressings where the skin is under shear tension stress. Lastly the

bottom right picture is a classic representation of skin maceration where excessive moisture is trapped underneath the medical tape/dressings that causes mechanical softening of skin and making it more prone to damage.

It is also notable that MARSI can be a special concern for certain population groups. As an example, the extremes of the age spectrum (i.e. geriatric patients and neo-natal) can be especially prone to MARSI. Also patients with already compromised skin, for example certain diabetic patients or patients who went through chemical/radiation therapy, are other groups that are more prone to MARSI. In addition, repeated application and removal of medical adhesive on the same skin area typically cause more serious MARSI. <sup>(3)</sup>



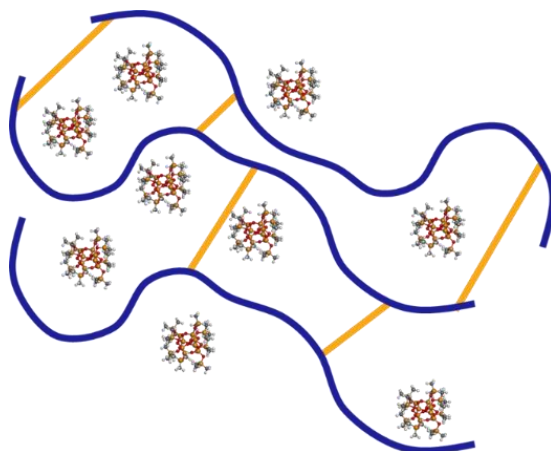
**Figure 1.** Examples of Medical Adhesive-Related Skin Injury (MARSI)

## Medical adhesives

Medical adhesives can be made from a variety of materials, such as (natural and synthetic) rubber including hydrocolloids, poly acrylates, hydrogels and polyurethanes, and silicone. Among these different adhesive technologies, silicone is emerging as the newest class of adhesive materials and is recognized as the adhesive class that can be formulated to provide the best gentle-to-skin performance. In addition, silicone is a material known for its good biocompatibility, inertness, and high breathability. Silicone PSAs have been traditionally used in industrial applications, where they can deliver unique properties such as wide-temperature performance window (both high and low temperature), general good adhesion to low surface energy substrates, quick adhesion (especially useful for splicing), and low adhesion build over time/temperature.

Traditional silicone PSAs comprise of silicone gum and tackifying resin. Different chemistries can be applied to provide a crosslinked PSA such as peroxide-cured, Pt-catalyzed hydrosilylation, and radiation-cured. Typical silicone adhesives used in medical application are silicone gels that have much lower modulus than silicone PSAs. In addition, while silicone PSAs typically contain 50-60 weight percent tackifying resin (“MQ-resins”), silicone gels used in medical application contain none or much lower level of tackifying resin. Figure 2 is a schematic of our new silicone gentle to skin adhesive technology. The blue lines depict the poly-di(alkyl)-siloxane, where if all alkyl groups are methyl, then the polymer is poly-dimethyl-siloxane (PDMS). The small molecules in the schematics are MQ tackifying resins, and the yellow lines represents crosslink points “stitching” the polymer network together. One can describe the

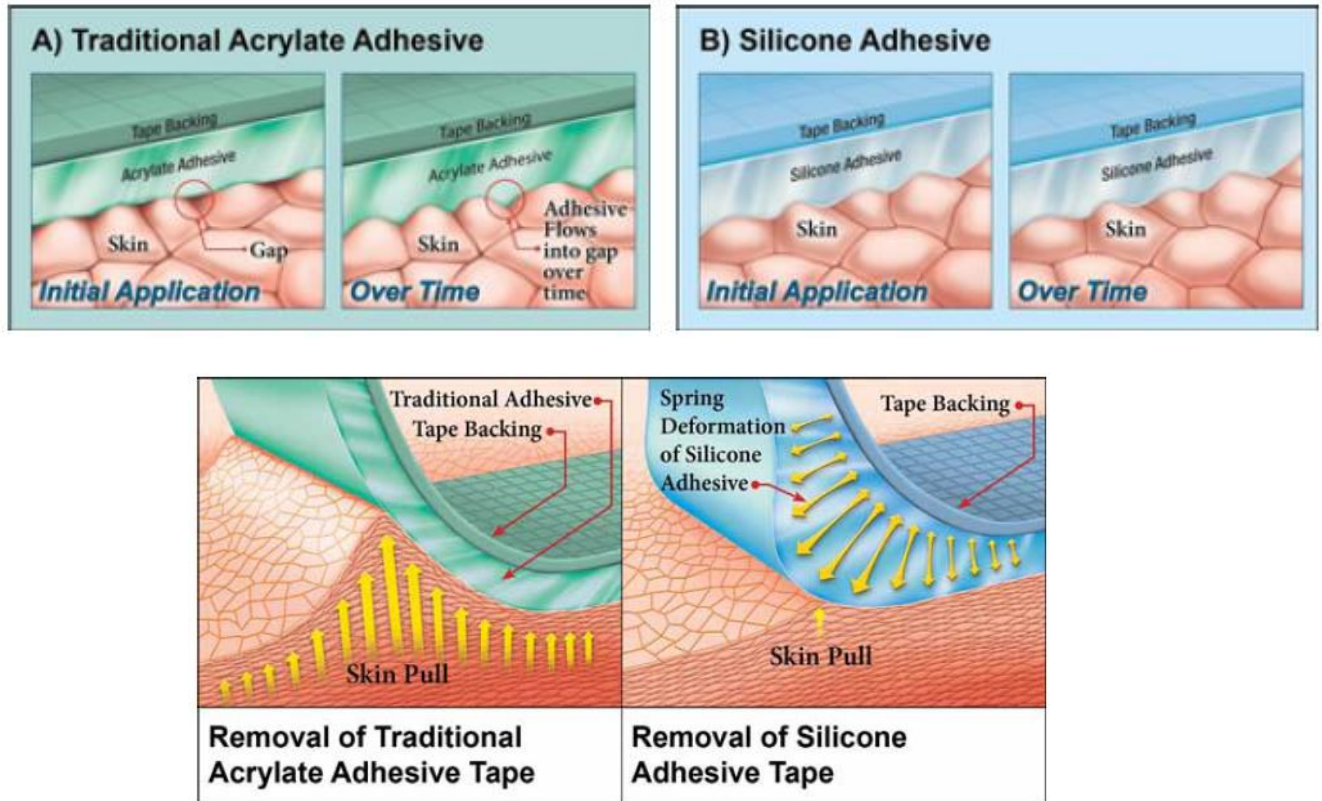
material as a cross-link adhesive gel. Our proprietary technology allows us to create medical silicone gel adhesives that have tailor-made adhesion properties.



**Figure 2.** Schematic of silicone gel gentle to skin adhesive

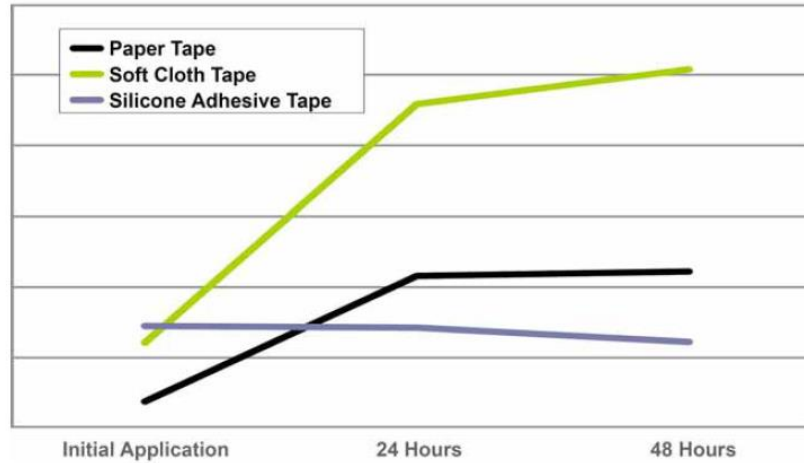
### **What makes Silicone gel a gentle to skin adhesive?**

As mentioned above, medical adhesives can be made from a large variety of polymeric materials such as poly acrylates. Figure 3 below illustrates the difference between traditional poly acrylates-based and silicone gentle to skin adhesive.<sup>(4)</sup> The discussion is easier to divide into 2 parts, namely bond-making and bond-breaking. In classical adhesion science model, a PSA material is visco-elastic, i.e. it has both viscous and elastic mechanical characteristic. A PSA material has viscous component so that it can flow and wet out to make the bond with the adherend. It also has elastic characteristic to resist bond-breaking from the adherend. Here in bond-making, traditional acrylic medical adhesives tend to flow into the contours of the skin and around hair over time, resulting in higher adhesion build over time, and pain when hair and stratum corneum being removed at bond-breaking when the adhesive is removed. Silicone gel adhesive has low surface energy and more importantly low modulus, which allow it to quickly wet-out skin to form a maximum bond. Silicone gel adhesive is more elastic than traditional acrylic adhesive, especially at long time-scale. This eliminates the cold-flow of the adhesive around hair and skin cells. At bond-breaking, the lower modulus of silicone gel adhesive manifests itself in lower peel strength and hence more gentle adhesion. Lastly the lack of either physical interpenetration or chemical interaction with skin and hair result in no or lower adhesion build over time.



**Figure 3.** Schematic comparison of mechanism of adhesion of traditional acrylate and gentle to skin silicone adhesive

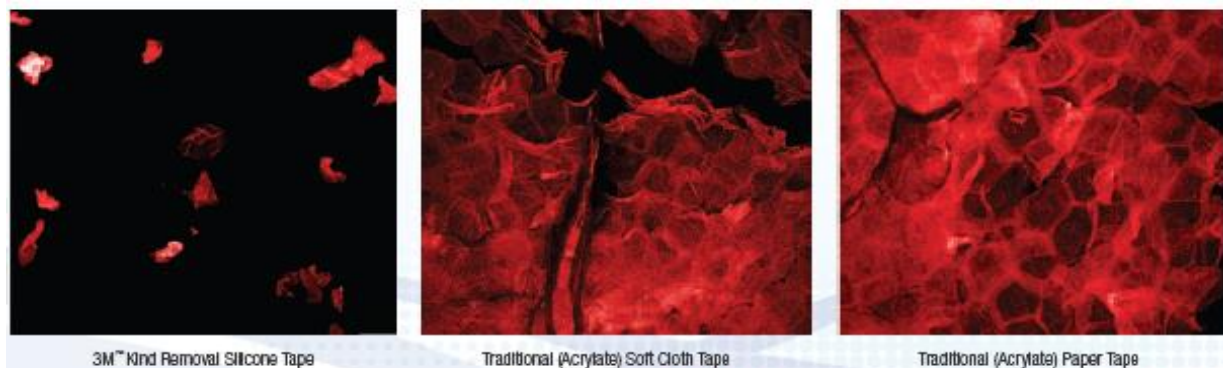
The phenomenon described above is also supported by skin adhesion data from clinical studies. Figure 4 below shows the typical skin adhesion profile over time of common medical tapes.<sup>(5)</sup> Tape samples were applied in a standardized manner to the backs of healthy volunteers. The tapes were removed after various dwell times on the skin with an automated peel instrument. The 2 tapes with acrylate adhesives (labelled paper tape and soft cloth tape) exhibited 2 to 4 times increase in skin adhesion after 24 to 48 hours of dwell time, while the adhesion strength of the silicone tape remained relatively constant.



**Figure 4.** Typical Skin Adhesion profiles of common medical tapes

### Quantifying gentleness

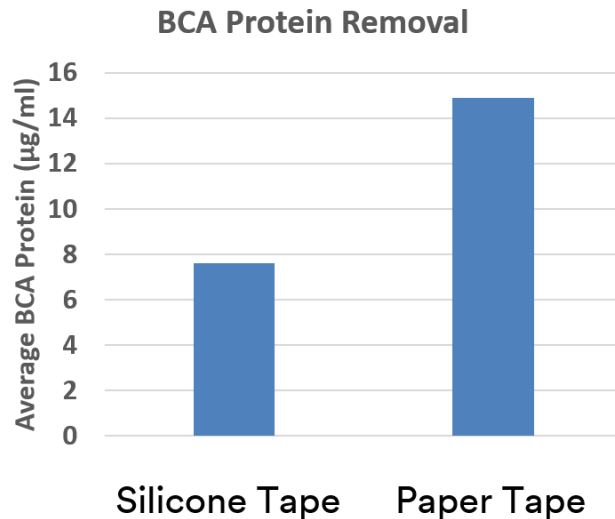
As one would expect, it is not trivial to define what gentleness means. Perception such as pain can be subjective. One approach is to examine the skin trauma caused by the adhesives. Figure 5 below shows confocal microscopic images of medical tape surfaces after being removed from a healthy volunteer. The images show skin cells and hair in red that were stripped on removal of three tapes. The left panel is from silicone gentle to skin adhesive, while the middle and right panels are traditional acrylate tapes. The gentle to skin silicone adhesive clearly removed less skin cells and hair from skin.



**Figure 5.** Skin cell removal visualization.

While the confocal microscope images above shows a qualitative difference between silicone adhesive and traditional acrylate adhesives and it is an easy way to visualize, it is not a quantitative measurement. Efforts have been made to attempt to quantify adhesive removal gentleness, or trauma caused by the medical adhesives. One approach was quantification of skin protein (keratin) removal by the adhesive. This method used a bicinchoninic acid (BCA)

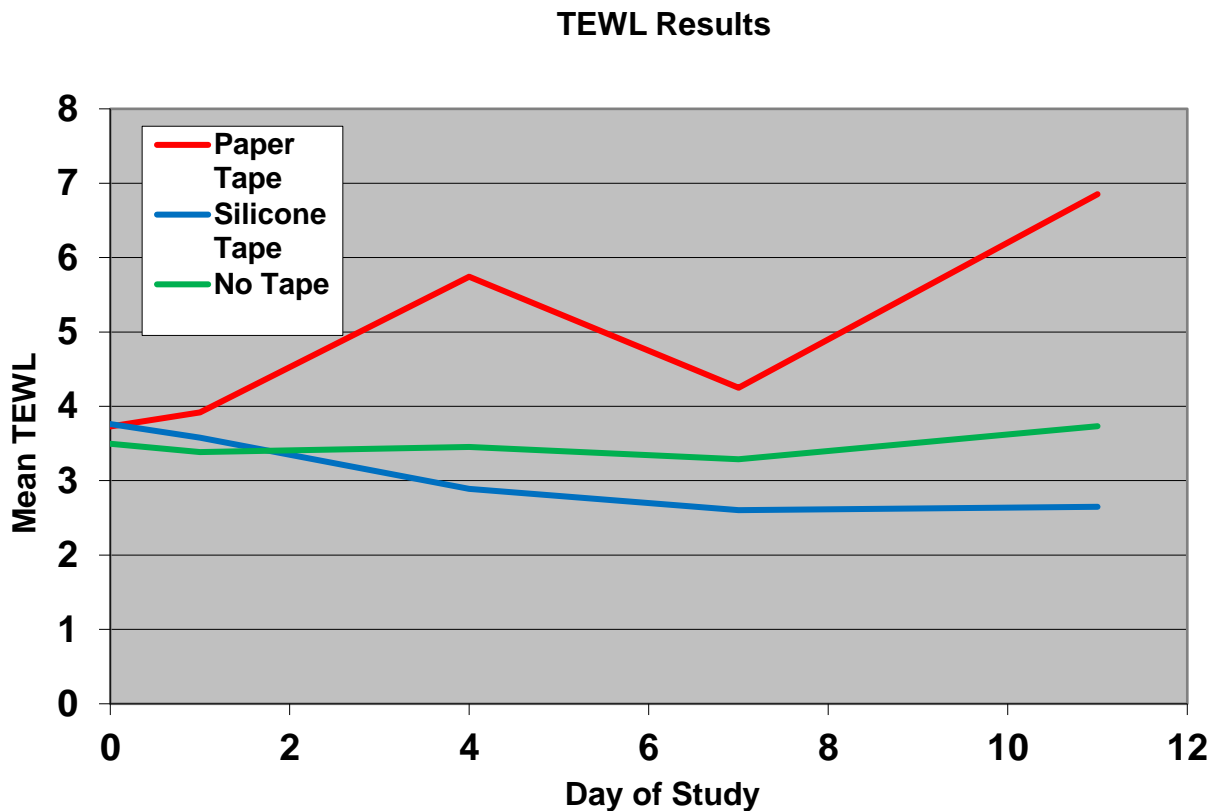
colorimetric detection and protein quantification assay.<sup>(4, 6)</sup> It determines the concentration of skin proteins extracted from the medical adhesive tapes after being removed from skin. Figure 6 below shows the results of the BCA removal analysis. Less skin protein was removed by the silicone adhesive tape compared to the traditional acrylate paper tape. The result is also consistent with the qualitative skin cell visualization results described above.



**Figure 6.** BCA protein removal analysis

While the above described methods can give good indications if a medical adhesive is gentle, they are indirect methods. A more direct way to assess skin trauma is called Transepidermal Water Loss (TEWL), which is a well-established method in the literature.<sup>(7-9)</sup> The principle of this method is very intuitive. Skin (Stratum Corneum) acts as a water barrier. Human body loses water vapor to the environment at a certain rate. When skin trauma is caused and layers of the epidermis are removed (e.g. by an aggressive medical adhesive), the rate of TEWL would increase from the baseline level.

Figure 7 below shows the result of our TEWL study,<sup>(10)</sup> again comparing the new silicone gel adhesive (labelled “Silicone Tape”) and a traditional acrylate adhesive (labelled “Paper Tape”). In this study, the 2 tapes were being applied and removed daily (except over weekend, a total of 9 applications and removals of tapes over 11 days). TEWL was measured at days 1, 4, 7 and 11. The y-axis is the net change of mean TEWL from baseline measurements (at Day 0). Skin positions with no tape applied were also monitored as a control. As evident from the data, the silicone tape showed consistent significantly lower TEWL than the paper tape with traditional acrylate adhesive at all time points. This indicates the silicone adhesive caused less disruption to the epidermis barrier, causing less trauma and is gentler to skin. The TEWL values of the silicone tape are the same or lower than the untreated control sites. It is worthy to note the differences observed here are statistically significant but small, indicating the paper tape selected for this study was also not causing clinical relevant skin trauma.



**Figure 7.** Transepidermal Water Loss (TEWL) study results

## Conclusions

In conclusions, while the primary function of medical adhesives has always been adhering and good securement to skin, traditional medical adhesives can caused skin trauma and patient discomfort. Medical adhesive-related skin injury (MARSII) is a phenomenon needed to be addressed. Silicone gel adhesives were developed as a new PSA technology to address this problem. Clinical research data supported that silicone gel adhesives are gentler than traditional acrylate adhesives. More advances are required to broaden the applications of silicone gel adhesives.

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### **Acknowledgments**

This research and development effort was supported by the 3M Company. The author thanks the entire 3M Kind Removal Silicone Tape product development team, especially Michael Determan, Simon Fung, Nancy Koski, Katri Huikko and Fang Zhou.