

Considerations for Adhesion to Skin

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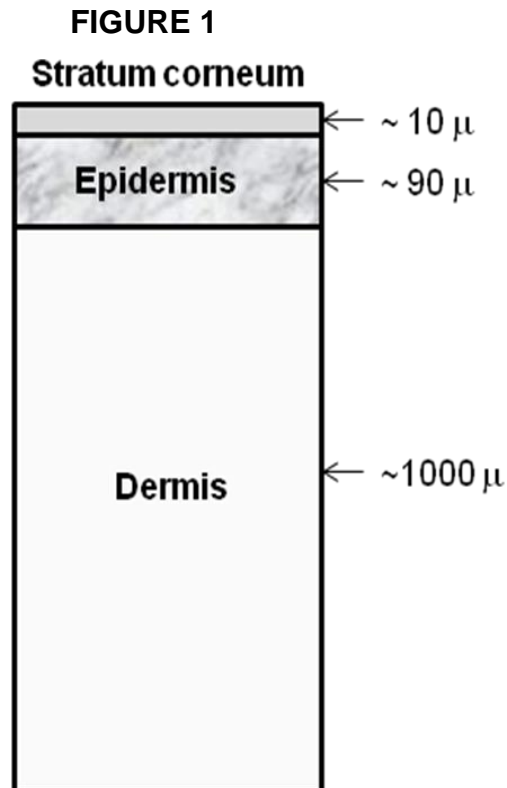
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ABSTRACT

For this paper, some considerations regarding adhesion to skin will be discussed. We will begin with a background on skin biology and discuss some of the unique attributes which pose many challenges for adhesion; that will be followed by some general adhesive and safety requirements for adhering to skin. Lastly, some rheological tools for evaluating adhesives for skin applications will be discussed.

INTRODUCTION

To begin our discussion, we must first understand the complexity of the substrate which we are trying to adhere to. Skin is one of the largest organs of the body and is also one of the most challenging surfaces to design an adhesive to adhere to. Listed in figure 1 below is a cross section of skin.¹



The outermost layer, called the stratum corneum, is composed primarily of sebum and dead skin cells. This outermost layer is the first line of defense for the body, as it provides lubrication and hydration as well as impeding the entrance of microorganisms, UV radiation, electric current, and toxic substances.²

Sebum generally contains the following materials. The amount and composition can vary from person to person depending on age and overall health conditions.³

- triglycerides
- Free fatty acids
- Wax esters
- Squalene
- Cholesterol esters
- Cholesterol

The major role of the sebum is that of protection and preserving moisture. The skin also naturally transports water across this barrier and this phenomenon is referred to as transepidermal water loss (TEWL). The amount of water transported can be measured with a Tewameter® and is expressed in units of $\text{gm}^{-2}\text{h}^{-1}$. A typical value for the forearm is $9.7 \text{ gm}^{-2}\text{h}^{-1}$ in contrast the value for the palm is $101.4 \text{ gm}^{-2}\text{h}^{-1}$.⁴

Another aspect of skin is the variances in topography. In addition to the many curves of the human body, on the surface there are many peaks and valleys that the adhesive must fill to adhere to properly. The images below (Figures 2 & 3) are an example of the surface topography of skin. The images were taken with a SONY solid state B&W, 50 mm lens/30mm extension.

FIGURE 2

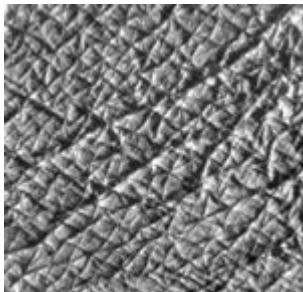


FIGURE 3



To summarize the basics of the substrate, it includes a surface that is not flat or smooth, varies from person to person, and contains varying amounts of water and other organic material.

GENERAL PROBLEM STATEMENT

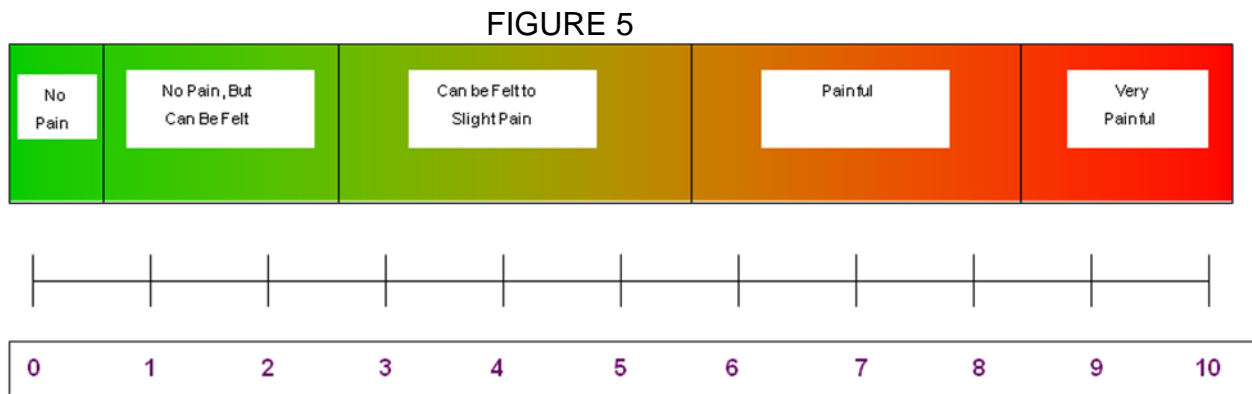
There is a need for an adhesive that will safely adhere to the surface of the skin, not cause pain upon removal and stay in place for a particular skin application.

SAFETY

This is one of the first critical hurdles for any skin application. In general, adhesives need to meet FDA 21 CFR 175.105 for food contact and CONEG for heavy metals and will subsequently be tested according to ISO 10993 for medical devices prior to any testing on human subjects.

PAIN UPON REMOVAL

Pain is a subjective phenomenon; therefore, one of the only ways to predict this is to test the materials on human subjects and rate the pain upon removal using the following scale in Figure 5.⁵



Ideally, one should try to get a minimum of 20 subjects of varying skin types to rate the pain upon removal of a given article. In addition, the amount of adhesive, wear time and backing materials would be specific to a particular application. These types of tests are very costly and time-consuming and not very ideal to use as a screening tool early in the development process, when many different types of adhesives could be considered for use on the skin.

ADHESIVE SELECTION

There are many types of adhesive chemistries that are used for applications on skin. These include hot melt PSAs based on styrenated block co-polymers (HMPSA), acrylics, synthetic rubber, silicones, hydrocolloids and hydrogels. In the early phase of development, a user of adhesives for skin applications is typically limited to *in vitro* data provided by the supplier. The list below is an example of data that would be supplied on a technical data sheet:

- Peel Adhesion
- Shear
- Viscosity
- Heat Stability (HMPSA)

- Color

Many adhesive suppliers and tape manufacturers routinely provide peel adhesion data using PSTC-1. Although this standardized method is used, the data is not consistently reported. The thickness of the adhesive and backing material is usually not the same from one supplier to the next. For example, a bulk adhesive supplier may report its standardized peel adhesion data using an adhesive thickness of 0.001” and PET backing thickness of 0.001” whereas a tape manufacturer may report the data specific to the tape, so the thickness is variable and the tape may also contain a carrier film. Based on limited data and descriptions provided by the suppliers, it is difficult to select the most appropriate adhesive desired for our application. The next step would be to assess the peel adhesion of all the adhesives using the same thickness, backing and test method. Several commercially available adhesives of varying chemistries that are used for skin applications were selected for an initial screening. The peel adhesion data for these adhesives was tested following PSTC-1 and is reported in table 1. All adhesives were prepared by transferring the adhesive films to 2 mil PET as a backing and tested by applying to stainless steel (SS) and low density polyethylene (LDPE) plates, rolled down with a 4.8 # roller (2 passes) and conditioned at CTH conditions for 15 minutes prior to testing. The adhesives were tested using an I-MASS slip/peel tester at 12”/min.

TABLE 1

ID	BACKING	ADHESIVE THICKNESS (inches)	PEEL ADHESION SS (lb/in)	PEEL ADHESION LDPE (lb/in)
A	2 mil PET	0.002	7.66 CF	2.71 AF
B	2 mil PET	0.002	7.40 CF	6.20 CF
C	2 mil PET	0.002	10.43 CF	5.41 AF
D	2 mil PET	0.002	5.80 CF	5.33 CF
E	2 mil PET	0.002	5.82 AF	3.23 AF
F	2 mil PET	0.002	7.77 CF	7.30 CF
G	2 mil PET	0.002	0.34 AF	0.5 AF

CF = cohesive failure

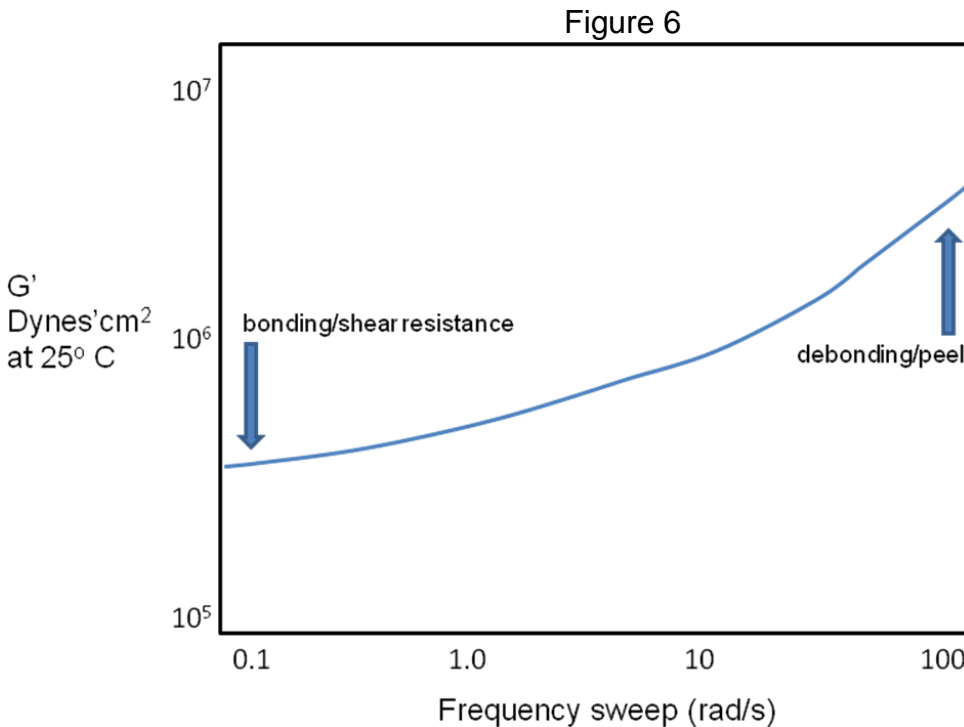
AF = adhesive failure

The standardized peel data is useful to help differentiate the adhesives; however, with the exception of sample G, all of the adhesives, regardless of chemistry, were in the 5-10 lbs range of peel strength on SS. Also of note is that all of the adhesives exhibited cohesive failure on SS except samples E and G. The affinity to skin versus SS will likely be significantly different so it is difficult to predict from SS data what the failure mode on skin would be for these adhesives. Most skin applications will require adhesive failure as the primary mode of failure. The initial peel data along with material cost and manufacturing capability can help to prioritize which adhesives to screen further.

RHEOLOGY

The commercially available adhesives under consideration for this skin application all exhibit viscoelastic behavior. Rheological analysis is a method for determining the viscoelastic properties.

Chu⁶ explains that initial bonding occurs at low deformation when the adhesive makes contact with the surface, whereas debonding is a high rate process at high deformation. Figure 6 illustrates this in which adhesives are analyzed at varying frequencies at room temperature.



Chang^{7,8} introduced the concept of viscoelastic windows to identify different types of pressure sensitive adhesives. The windows are established by plotting coordinates of the adhesive into quadrants at 0.01 and 100 rad/s which represent the typical time scales for adhesion testing. The advantages of this approach are that these frequencies are accessible with our current instrumentation and are much quicker to obtain versus a standard time-temperature superposition master curve. The quadrant of interest for this exercise is in the lower left quadrant, which represents adhesives with lower modulus and lower dissipation. It is assumed that adhesives that occupy this quadrant would be more conformable and ideal for use on the skin.

EXPERIMENTAL

All of the bulk adhesives were analyzed on a TA instrument AR-1000 rheometer using parallel plate clamps. The samples were all 2.0 mm thick and the frequency sweeps were performed between 0.01 and 100 rad/sec at 37 °C which represents typical body temperature. Figure 7 contains frequency sweeps for all the adhesives under consideration. There were many different slopes and modulus at high frequency observed, so the data was split into two groups. Figure 8

contains the adhesives that had higher peels on SS (≥ 7 lbs) and Figure 9 contains the adhesives with lower peels on SS (< 7 lbs).

Figure 7

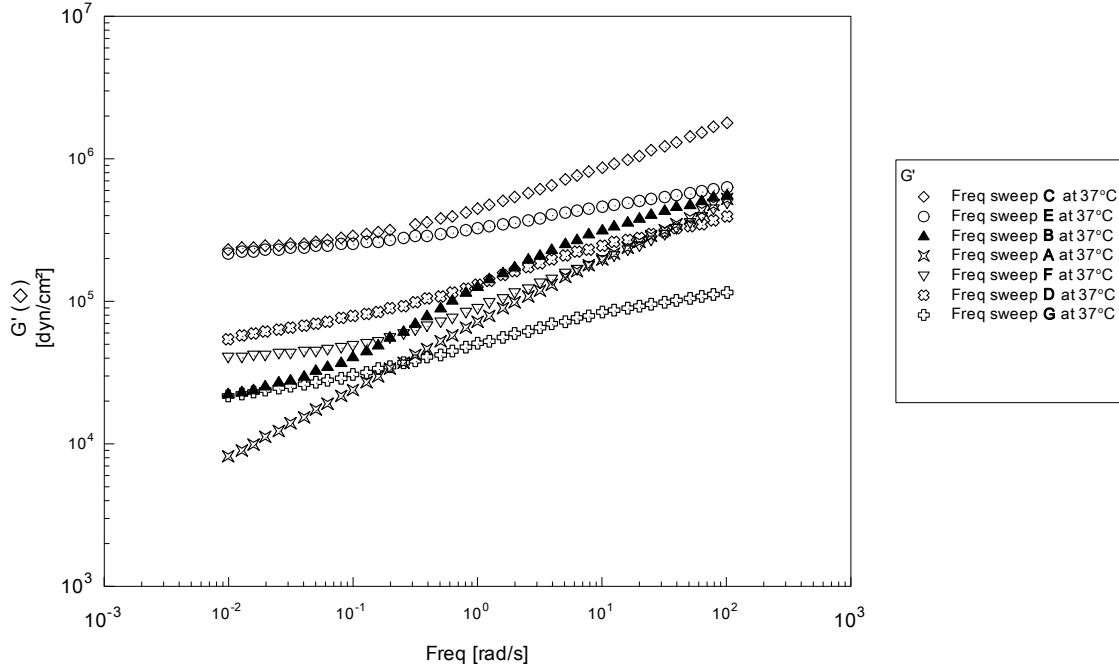


Figure 8

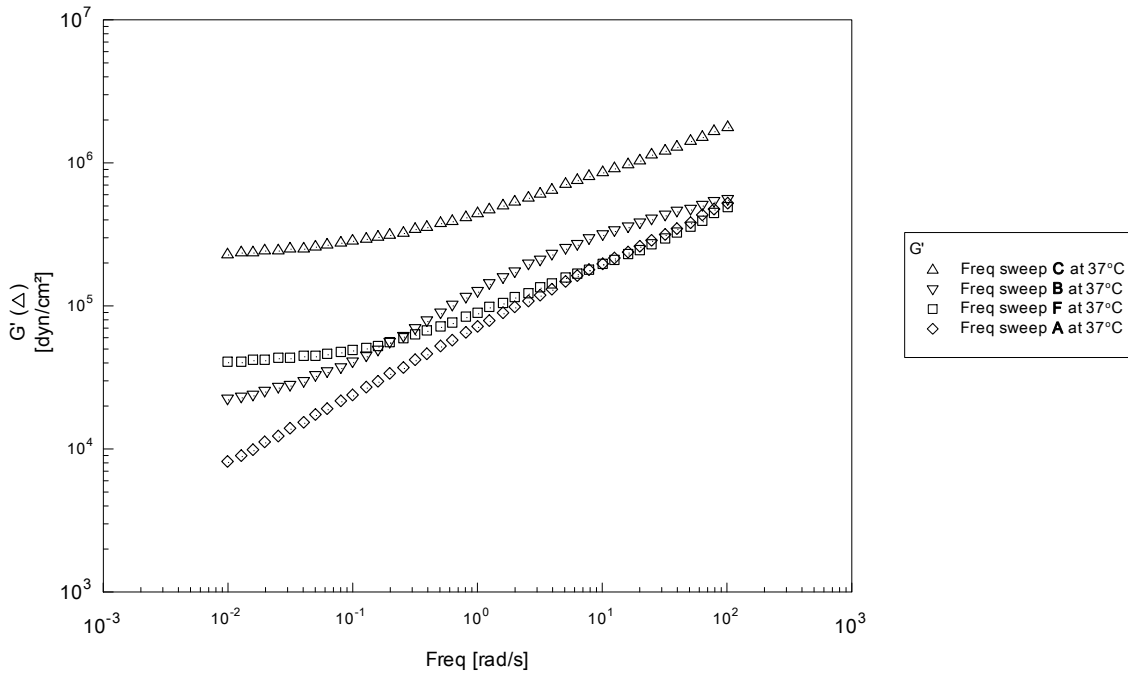
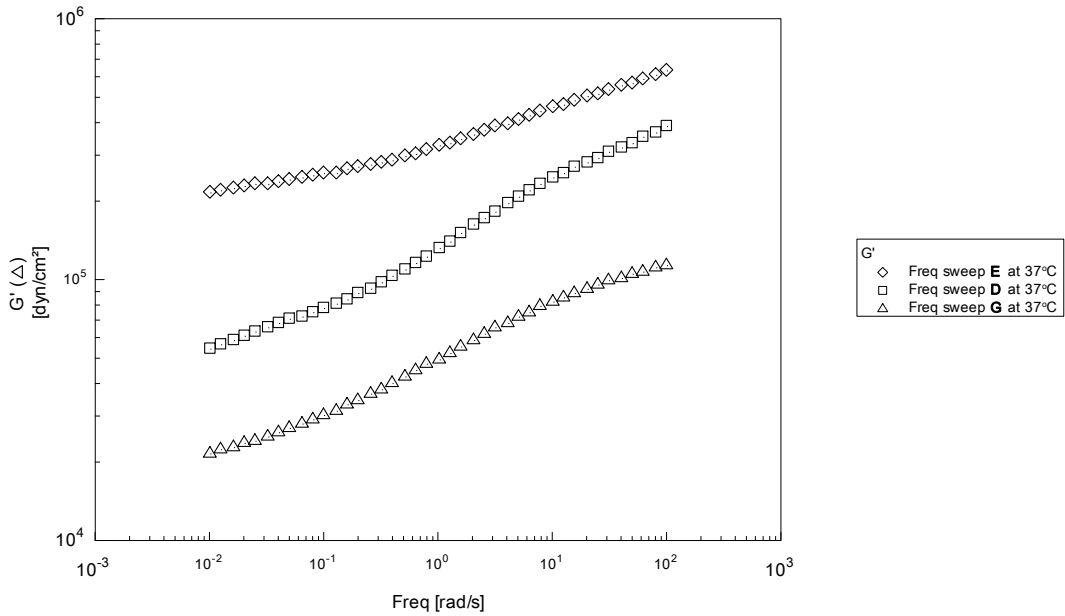


Figure 9



The viscoelastic windows were plotted for all of the adhesives under consideration. The quadrants were constructed as described by Chang^{7,8} in the following manner: coordinate 1 G' at 0.01 rad/s, G'' at 0.01 rad/s; coordinate 2 G' at 100 rad/s, G'' at 0.01 rad/s; coordinate 3 G' at 0.01 rad/s, G'' at 100 rad/s; coordinate 4 G' at 100 rad/s and G'' at 100 rad/s. The coordinates are all plotted on a log-log cross plot of G' and G'' . The adhesives were again split into two groups, Figure 10 contains the lower peel adhesives ($<7\text{lbs}$) and Figure 11 contains the high peel adhesives ($\geq 7\text{lbs}$).

Figure 10

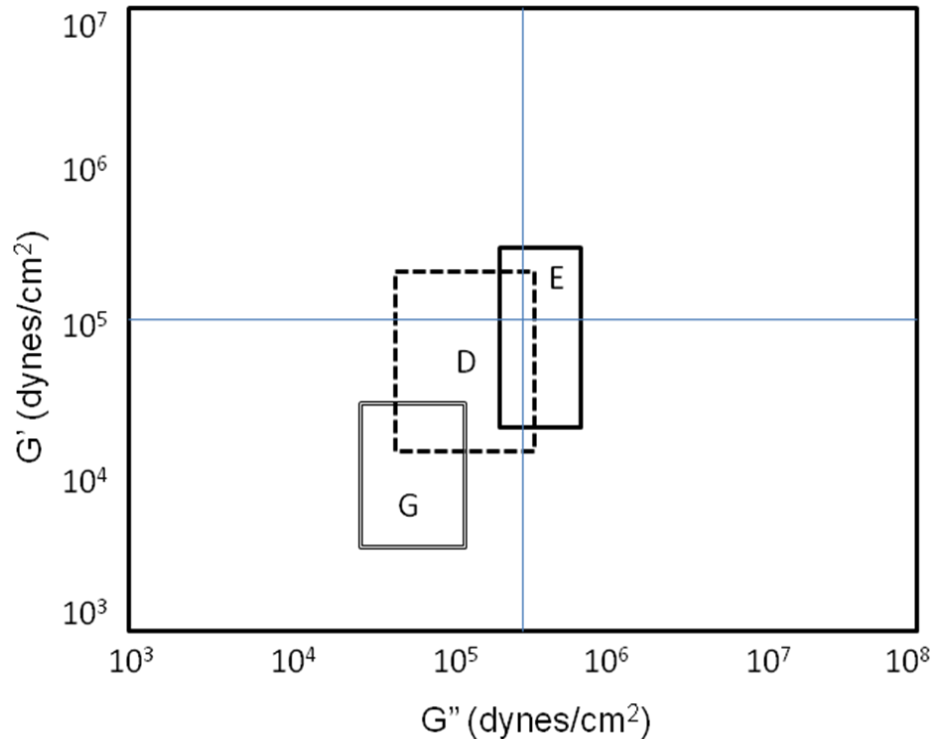
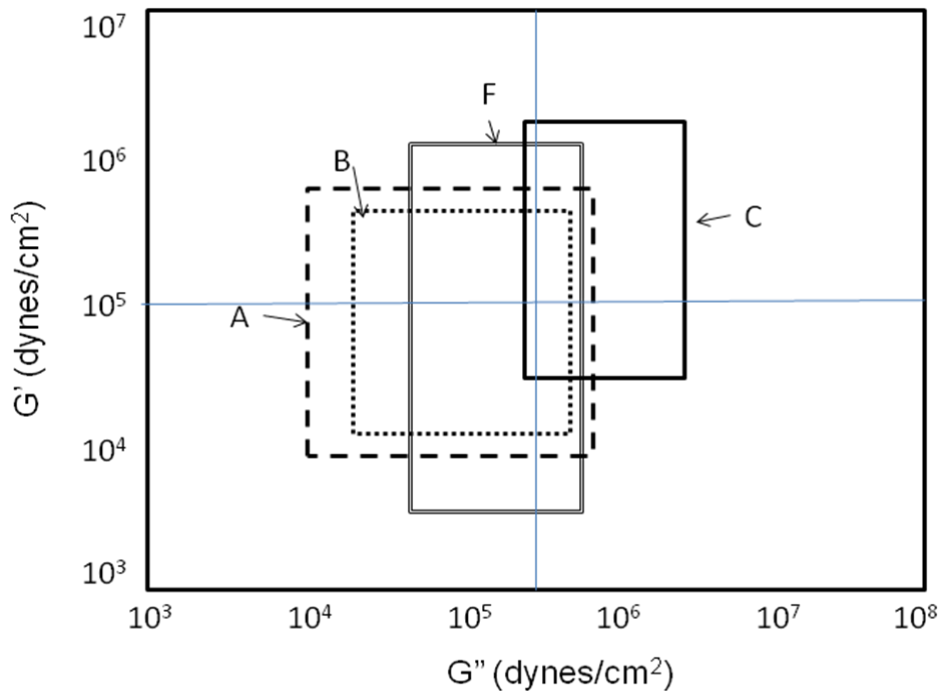


FIGURE 11



RESULTS AND DISCUSSION

The trend in modulus at high frequency seems to correlate well to the standardized peel data reported in Table 1. For example, the highest peel value on SS was reported to be 10.39 lbs for adhesive C and this adhesive had the highest G' at high frequency in comparison to the other adhesives tested. On the contrary, the lowest peel value on SS was reported to be 0.34 lbs for adhesive G and this adhesive had the lowest G' at high frequency in comparison to the other adhesives screened. The other noteworthy observation of the adhesives that were tested is that the modulus (G') in the frequency sweep data for the lower peel strength adhesives appears to be less impacted by changes in frequency.

Most of the adhesives analyzed occupied a portion of the lower left quadrant but seemed to fall more toward the center area. According to Chang^{7,8} this center region is where a general purpose PSA would be defined. The only adhesive that seemed to fully occupy the lower left quadrant was adhesive G.

Adhesive G is a HMPSA and was selected for testing on human subjects for a particular skin application. The subjects wore the articles for four hours and the pain upon removal was reported. The average pain upon removal reported for all subjects was a '4' which correlated to slight pain. The articles also stayed in place during the test. It is likely that the other adhesives under consideration would have stayed in place equally well based on the high modulus values at high frequency; however, they would have likely rated higher on the pain scale.

CONCLUSION

The original goal of this exercise was to identify an adhesive that was safe to use on skin, stayed in place and not cause pain upon removal. Due to complexity and significant variability, it is difficult to predict the performance of adhesives on all skin based on standard *in vitro* test methods. This study showed that the analysis of viscoelastic behavior can be a useful tool for screening adhesives of varying chemistries and properties for skin applications and help to prioritize adhesives for *in vivo* testing in a particular application.

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