Comparison of Silicone Adhesives in Skin Contact Applications: How Material Properties Influence Adhesive Performance and Wear

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Statement of Purpose: Silicone adhesives are widely used in a variety of medical applications, including wound care dressings, scar care treatments, medical device attachment and in transdermal drug delivery. DuPont has developed several different types of silicone adhesives designed to perform in these varied applications. The primary performance objective for these adhesives is their reliable and secure adhesion to skin. However, the skin is a highly variable substrate that is difficult to fully recreate in a lab. Therefore, a variety of alternative and complementary techniques are employed to evaluate these adhesives, including peel adhesion to stainless steel and polycarbonate substrates, tack, penetration testing, rheology and moisture vapor transmission (MVTR). These results are then bolstered by wear and repositionability tests on human volunteers. This study aimed to evaluate three families of silicone adhesives of different chemical compositions and material properties for their performance in skin contact applications. The selected materials were silicone soft skin adhesives (SSA), pressure sensitive adhesives (PSA) and hybrid soft skin adhesives (hSSA). SSAs are lightly crosslinked silicone networks, cured via a platinum-catalyzed hydrosilylation reaction. The resulting adhesive is a transparent, tacky, and gel-like material. PSAs are a thermoplastic, polycondensation-cured, bodied MQ silicate resin-in-polymer system. They are offered in a variety of solvents and are similarly tacky, transparent materials. The hSSA is a hybrid system, wherein an SSA base network is loaded with an MQ silicate resin. This adhesive is also transparent and gel-like.

Methods: *Laminate Prep.* SSA and hSSA laminates were prepared by blending parts A and B at a 1:1 ratio and applying the mixture to a polyester backing and using a coater to achieve a final thickness of 6- or 10-mil. Laminates were cured at 130ºC for 4 minutes. PSA laminates were coated at 4 mil (2 mil dry) on a polyester backing. The adhesive de-volatilized at room temperature for 5 minutes and at 100ºC for an additional 5 minutes. *Adhesion.* SSA, hSSA, and PSA laminates were cut into 1" x 5" strips, applied to a stainless steel (SS) or polycarbonate (PC) and allowed to dwell for 20 or 30 minutes, respectively. 180º peel adhesion was evaluated using a TA Texture Analyzer for PC or an Instron for SS. *Penetration.* Cups of 100g of SSA and hSSA were cured at 130ºC for 1 hr. Penetration was measured using a penetrometer, which measures the depth the tip penetrates a known mass of material over a specified time. *Wear Studies.* Representative patches were prepared with a layered polyurethane and cotton backing and 13-14g of weight. Volunteers wore patches on their chest for 14 days. Duration of wear was recorded. *Repositionability.* Peel force of the SSA and hSSA was measured after a 15-min dwell on the forearm of volunteers. The strip was re-adhered, dwelled for 15 minutes and peel force measured again. This measurement was repeated up to 5 times.

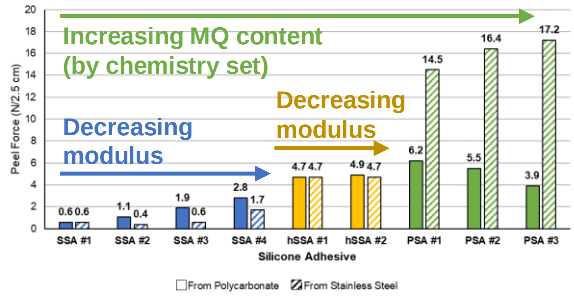

Figure 1. Adhesion of DuPont™ Liveo™ silicone adhesives to polycarbonate and stainless-steel substrates.

Results: The peel adhesion force of silicone adhesives from both stainless steel (SS) and polycarbonate (PC) substrates increases with increasing MQ incorporation, with the PSAs having both the highest MQ content and the highest adhesion levels – 14.5 – 17.2 N/in (SS) and 3.9 – 6.2 N/in (PC), with the SSAs having the lowest – 0.5 – 1.7 N/in (SS) and 0.6 – 2.8 N/in (PC). Within adhesive families, increasing penetration or lowering the modulus, generally increases the adhesion, as it improves the ability of the silicone to wet out the adhesive substrate and enable the intermolecular interactions that facilitate adhesion.

One formulation from each material family (SSA, hSSA, and PSA) was selected for a human wear study. Thirty volunteers wore weighted patches on their chests for 2 weeks. Wear duration, general comfort and other observations were collected. The PSA wore an average of 12 days, which was significantly longer than both the SSA at 8.9 days and the hSSA at 8.3 days. Interestingly, higher peel adhesion to substrates does not necessarily correlate to longer wear times. The hSSA, for example, has significantly higher adhesion than the SSA, but similar wear times. As expected, adhesion levels to model substrates alone are not the most accurate predictors of wear. Two additional factors have been considered: material modulus and adhesive repositionability. In order to facilitate adhesion, the silicone needs to be in intimate contact with the surface of the skin, a rough and irregular substrate. A softer material can better wet out the surface of the skin and enable this contact. Increasing the penetration by 2-fold between two hSSA formulations increased wear from 5 to 9 days. Repositionability is the retained adhesion after removal. In practice, it is the ability of the adhesive to re-wet out the surface of the skin after lift. The SSA material showed greatest retention of adhesion, 60% after 4 pulls, as compared to 45% for the hSSA. We postulate that improved repositionability can overcome lower initial adhesion and extend wear time.

Conclusions: Predicting wear of silicone adhesives is challenging and requires the combination of multiple laboratory tests and wear panel studies. Changing the chemistry, material properties, and patch construction can all impact wear and silicone adhesive performance.