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Applications

Silicone Gels for Wound Care

WACKER

High-Adhesion Silicone Gels for Wound Care with Less Pain

Atraumatic wound dressings generally contain gentle silicone gel adhesives. A current study shows that high-adhesion silicones can also offer wound care with less pain. At the same time, such products are also suitable for medical applications other than wound care.

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The era of advanced wound dressings began in the 1980s. Such multi-layered dressings (*Figure 1*) create optimum conditions for wound healing and are commonly used for the standard treatment of chronic and large-area wounds [1]. As a result, the adhesive properties of such dressings are attracting ever more attention. The aim is to adjust the adhesion to the skin surrounding the wound so that the wound dressing is reliably fixed yet can be removed painlessly, without trauma, and without damaging any tissue (*Figure 2*). This is usually achieved with a soft, gel-type silicone adhesive layer [2] [3].

An important aspect here is the wear time of wound dressings. A long wear time is not just beneficial for wound healing. It avoids frequent dressing changes and thus helps lower the nursing staff workload and reduc-

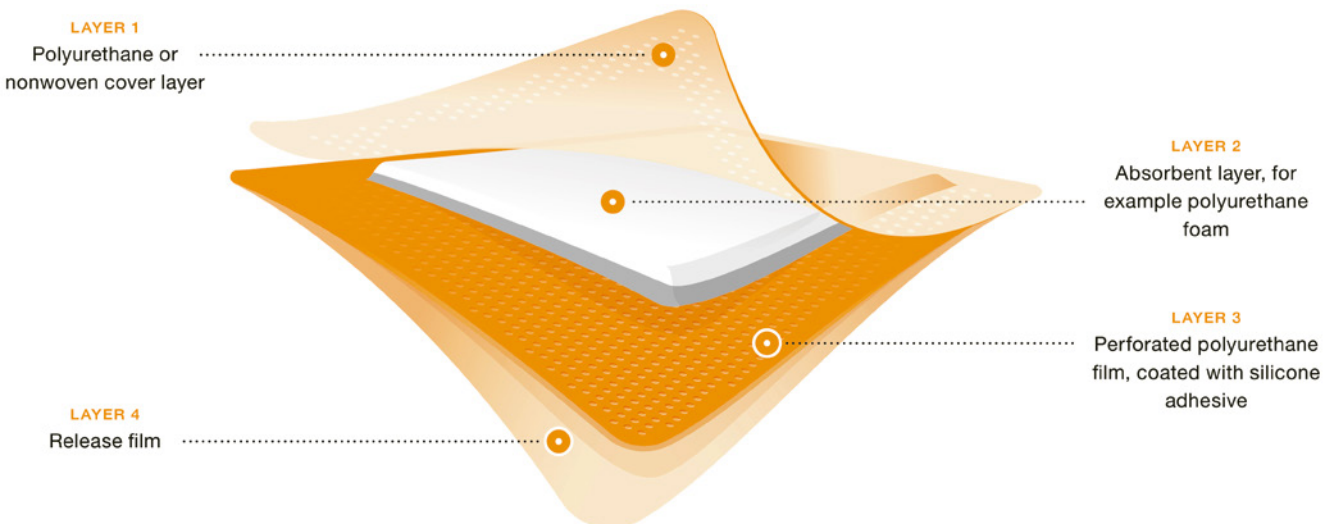

Figure 1 > Advanced wound dressings consist of several layers. The silicone adhesive layer lies directly on the wound. This is followed by a polyurethane carrier film, the back of which is coated with acrylate adhesive (Layer 3). This layer is perforated to allow wound exudate and blood to permeate to the absorbing layer (Layer 2). A polyurethane foam often serves as the absorbing layer. A cover layer (Layer 1), commonly a polyurethane film, closes this wound foam off to the outside. Until it is used, the wound dressing is covered with a release film (Layer 4), which can be pulled off easily.

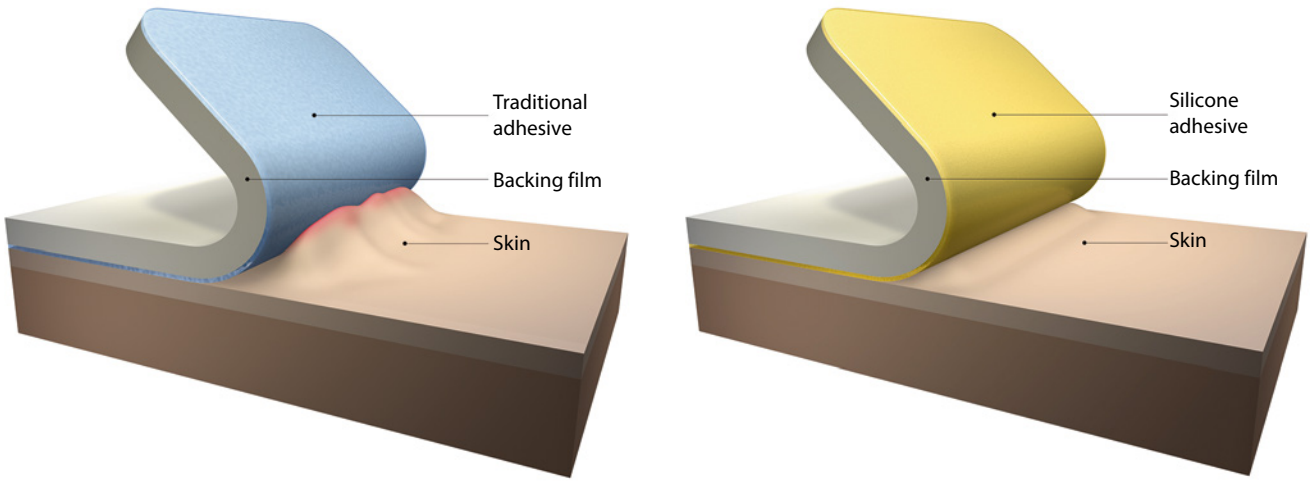

Figure 2 > A wound dressing that contains an adhesive layer made of acrylate or another conventional adhesive (blue) damages the skin on removal and causes pain (left), meanwhile a gentle silicone adhesive (yellow) allows for atraumatic and virtually pain-free dressing changes (right).

es treatment costs [4]. That's why wound dressing manufacturers are looking for adhesive layers that can extend wear time.
Another trend is the rising demand for adhesives that can be used to fix sensors, dosing devices for dispensing medication, base plates for colostomy bags or other medical devices on the skin. This requires reliable adhesion for a specified period, ranging from a few minutes to several days. The necessary adhesion strength depends on the expected wear time and the weight of the device to be fixed.
Both trends – extended wear times of wound dressings and reliable fixing of medical aids and dosing devices on the patient – necessitate adhesive gels with high adhesion strength. For this reason, Wacker has added high-adhesion grades to its portfolio of silicone skin adhesives. Despite their high adhesive strength, they make for gentle fixing to the skin and pain-free removal of the wound dressing or the fixed device.

Long-term test of wear properties

In a current study, Wacker shows that these at first seemingly contradictory requirements – strong adhesion and painless removal – can be fulfilled in practice. The study focused on the following questions: how does stronger adhesion affect wear time? Do residues of the silicone adhesive remain on the skin after removal? Does a higher adhesion strength cause greater pain on removal of the dressing?
In the study, foam wound dressings with two different adhesive layers were examined: the standard silicone adhesive Silpuran 2100 and the high-adhesion silicone gel Silpuran 2114. Silpuran 2100 is a gentle silicone skin adhesive. 90° peel tests on steel as per EN 1939 yield an adhesive strength of 2.7 N/2.5 cm, which is mid-range for silicone adhesives. For many years, the product has proven its worth in a variety of advanced wound dressings on the market. The second adhesive Silpuran 2114 is a high-adhesion gel that possesses a significantly higher adhesive strength of 3.5 N/2.5 cm.
Both adhesives are two-component formulations. These products crosslink at room temperature via a platinum-catalyzed addition reaction to form soft, highly flexible materials. These are conformable to the skin structure and movements and at the same time elastic, with a gel-like consistency. Their flexibility and the low surface energy typical of silicones ensure that a bond develops between the crosslinked silicone gel and skin. The adhesive's elas-

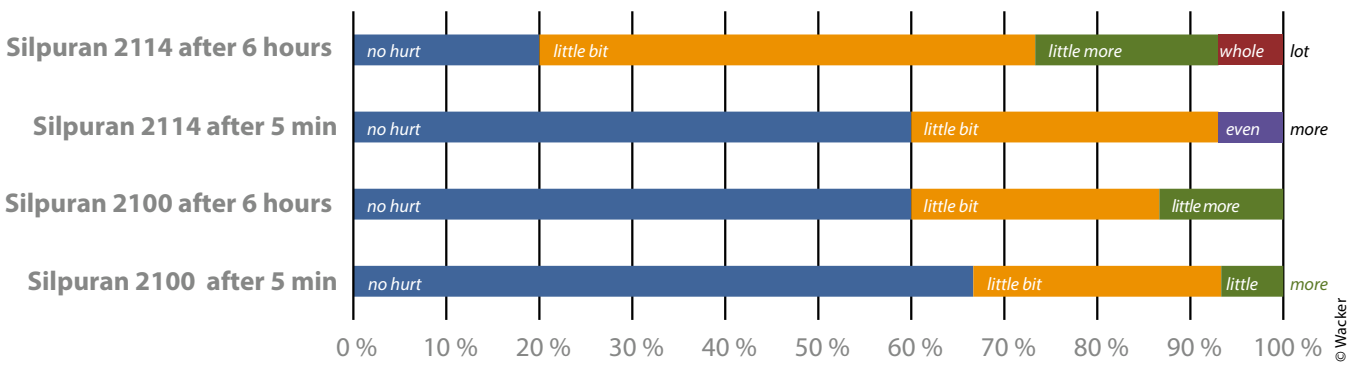

Figure 3 > Evaluation of pain perception on removal of wound dressings according to the Wong-Baker Faces pain rating scale (six pain levels).

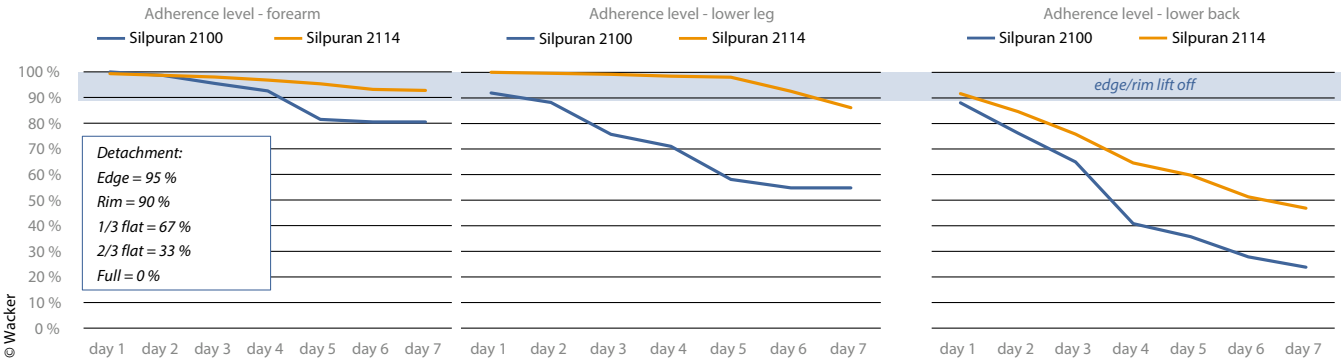

Figure 4 > Observed adherence levels of the wound dressings

ticity, on the other hand, allows the adhesive layer to be peeled off easily, generally leaving no residues. The flexibility is achieved through the wide-meshed network that the silicone gels form.
In Silpuran 2114, flexibility and elasticity are balanced so as to give the gel a greater adhesive strength than the standard adhesive gel Silpuran 2100. In its development, it was ensured that increasing the adhesive strength would not adversely affect the cohesion of the crosslinked material. As a result, cohesive failure can be avoided when removing the wound dressing. No residues of the silicone adhesive will remain on the skin. Whether this development goal can be achieved in practice was one of the questions the study focused on.

Properties and advantages of silicone adhesives

Silicone adhesives are hydrophobic and thus only adhere to dry skin. Therefore, a wound dressing with an adhesive silicone layer can lie directly on the wound, which is generally moist. It doesn't stick to the wound or to its edges. The dressings also won't knit with tissue newly formed during the healing process.
Silicone adhesive layers have another advantage: they can be repositioned. If a wound dressing is applied incorrectly, it can easily be peeled off and positioned again. Ideally, the dressing should adhere just as well to the skin as it did before. The study also investigated this expectation.

Test conditions

The study was conducted with 15 volunteers; sociodemographic data was not recorded. Foam wound dressings (7.5 × 7.5 cm) that were coated with 150 g/m² silicone adhesive gel were tested. The silicone layers were perforated; the perforation diameter was 4 mm. The wound dressings were applied to healthy skin on the forearm, calf and lower back in the lumbar spine region. Every day, all study participants examined the dressings applied to their bodies and noted their observations on a documentation sheet. Here, they recorded any detachments, the level of pain on removal and any residues remaining on the skin.
The participants were not restricted in their everyday lives. They were able to shower or bathe as normal and pursue sports activities. They were asked not only to record all sweat-inducing activities and contact with water on the documentation sheet, but also any other influences that may have impacted the wound dressings. The wear time of the wound dressings was limited to seven days.

Pain perception during detachment

In order to determine the pain perceived on removal, four wound dressings were applied to each participant's forearm. Two of these dressings were coated with Silpuran 2100 and two with Silpuran 2114. One wound dressing with each Silpuran grade was removed after five minutes, the two remaining dressings after six hours.

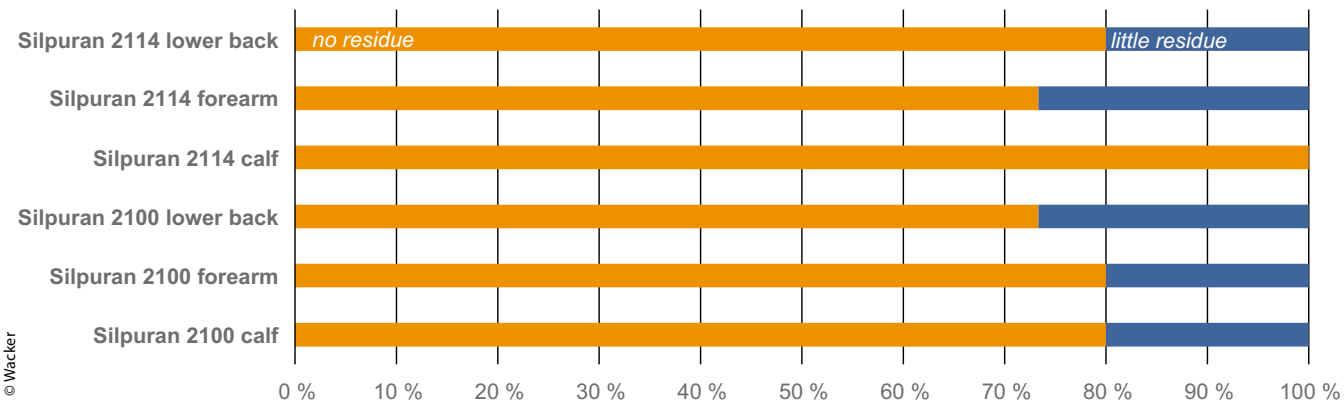

Figure 5 > Evaluation of residues that remained on the skin after removal. The dressings coated with the high-adhesion gel left no residues at all on the calf

The participants rated the pain that occurred on removal using the Wong-Baker Faces Pain Rating Scale [5] and recorded their perception of the pain (*Figure 3*). Averaged across both adhesive gels and both removal times, 52 % of participants rated the removal as completely painless. 97 % of participants perceived no pain or no more than minor pain. The majority of study participants said that they required more force and perceived a little more pain when removing the dressings coated with Silpuran 2114 compared to the dressings coated with Silpuran 2100.

Wear times of the wound dressings

In order to examine the influence of the adhesive properties on wear time, two wound dressings were applied to forearm, calf and lower back, where one was coated with a Silpuran 2100 adhesive layer, the other with a Silpuran 2114 layer.

The participants recorded any detachments on a daily basis and rated the size of the detached area according to a standard scaling, assigning a specific percentage of the dressing area. The standard scaling was based on the type of detachment: an edge lift-off was calculated as 5 and a rim lift-off as 10 % of the dressing area. A flat detachment was allocated either 33, 66 or 100 % of the dressing area, depending on how much of the surface was no longer attached.

The dressings were removed after seven days if they had not already come off on their own before then. Three-quarters of the study participants said that they had daily contact with water. The participants observed that a wound dressing's initial positioning had a significant influence on the level of adhesion. A correct, crease-free fit proved to be important. If water – in the shower, for instance – was able to get into the dressing's absorbent foam layer through creases created while the dressing was applied, the adhesion deteriorated.

Figure 4 shows the results for the wear time test on the three body parts selected for this study. It depicts the percentage of the wound dressing area that adhered to the skin, as a function of wear time. In general, the adhering surface area and thus the level of adhesion were greater for wound dressings coated with the high-adhesion Silpuran 2114 than for dressings coated with Silpuran 2100.

However, the dressings showed different levels of adhesion on the three body parts. On average, 90 % of the surface area of dressings coated with Silpuran 2114 still adhered to the forearm and calf after seven days. The level of adhesion for Silpuran 2100 was 70 % on these body parts during the same time period. With Silpuran 2114, surface detachments only appeared notably from the sixth day on. On the days prior to that, the study participants merely observed edge and rim detachments. Within the study period, not a single dressing detached fully on the forearm or calf in the case of the high-adhesion silicone gel.

The study participants registered considerably faster detachment in the lumbar spine region for both adhesive gels. A possible cause for the lower level of adhesion on the lower back is mechanical stress due to clothing or sports equipment, which led to creasing or partial and even complete detachment of the dressings.

A participant subgroup repositioned one of the wound dressings coated with Silpuran 2114 immediately after the initial application by peeling off the dressing and applying it again. Repositioning had no significant effect on the achieved wear time. Additional laboratory tests in which repositioning was simulated by repeated removal in a 90° peel test yielded the same result.

Residues after detachment

Once the dressings were completely removed, the study participants were asked to evaluate the previously covered skin areas with regard to adhesion and residues of the silicone adhesive (*Figure 5*). In terms of residues, the two adhesives behaved virtually the same. The study participants detected some residue in 19 % of all detached dressings and rated it minor. In 81 % of cases, no residue remained on the skin. Here, the assessment did not differentiate whether a wound dressing detached early by itself or whether it was actively removed after the seven-day test period. Residues were found more often after removal of wound dressings that had no longer adhered fully to the skin.

Supplementary laboratory tests

At Wacker's applications laboratories, the adhesive properties of the silicone adhesive gels were compared with those of two standard acrylate-based adhesives. One of the reference products was an adhesive marketed by its manufacturer as a sensitive product. Both steel test plates and the skin on a test participant's forearm were used as substrates.

The measurements show that the adhesive properties of the high-adhesion silicone gel Silpuran 2114 come close to the values for the sensitive acrylate-based adhesive (*Figure 6*). The adhesive gel can nonetheless be removed without trauma, as the study shows (*Figure 3*). Silpuran 2114 can thus also be used for applications other than advanced wound care.

The adhesion strength depends on the coating thickness of the adhesive gel. In order to test the influence of the layer thickness, 90° peel tests as per EN 1939 were performed on steel plates, whereby the coating weight of the silicone adhesive gels was varied. In these tests, Silpuran 2114 already achieved good adhesive strength at a reduced layer thickness: the layer needed to be only half as thick to, at minimum, achieve the adhesion of an adhesive layer made of Silpuran 2100. So, significantly thinner adhesive layers are possible with the high-adhesion silicone gel than with the standard adhesive. This is especially important for mass-market applications, such as sensitive adhesive plasters.

Summary

The current wear study confirms the known advantages of silicone adhesives in terms of pain perception on removal, absence of residues and repositioning. Both Silpuran 2100 and high-adhesion Silpuran 2114 facilitate virtually painless and residue-free removal of wound dressings.

For the treatment of chronic wounds, the market requirements on wear time for wound dressings can be fulfilled with both silicone adhesive gels. Both products do not restrict patients in their sporting activities. Frequent showering does not affect wear time in any way.

The study shows that longer wear times are possible with Silpuran 2114. The higher adhesive strength allows for a thinner coating than is the case for standard silicone adhesive gels which results in a cost benefit for processors. Furthermore, high-adhesion silicone gels find use outside of advanced wound care, too. Possible applications include medical tapes for fixing to very sensitive skin and reliable adhesive layers for medical devices that can be

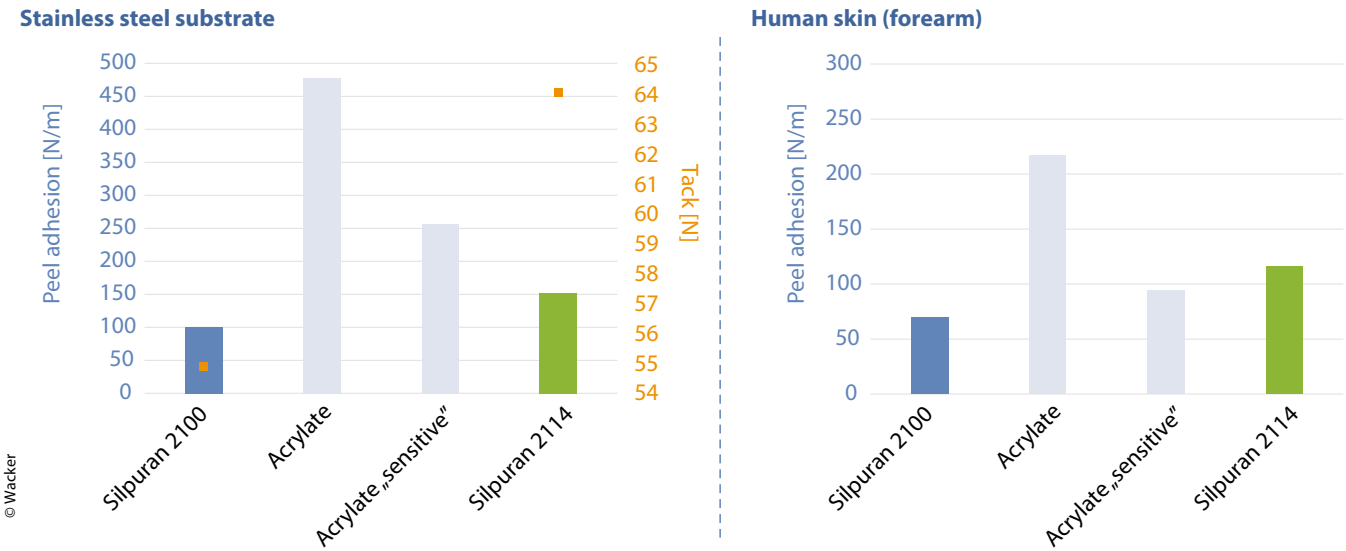

Figure 6 > Laboratory measurements of the adhesive properties of Silpuran 2100, Silpuran 2114 and two acrylate-based adhesives. The results of the 90° peel tests are represented by bars; the measured initial tack values are shown as small orange squares.

removed from the skin without pain or skin trauma.

The development goal of increasing the adhesive strength without impacting the cohesive strength was also achieved. The study shows that, despite stronger adhesion, Silpuran 2114 can be removed without residues. //

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