



WHITE PAPER | DR. THOMAS GRÖER, ANDREA BOGNER – May 2022

STUDY REGARDING THE WEAR TIME OF WOUND DRESSINGS

With Standard and High Adhesion Silicone Gel Adhesives

CONTENTS

1 AIM OF THE STUDY / MARKET REQUIREMENTS

2 BACKGROUND

3 STANDARD VS HIGH ADHESION SILICONE GELS

Evaluation of Wear Time, Repositioning, Pain and Residues

3.1 Method / Study Design

3.2 Study Results

3.3 Supplementary Laboratory Results

4 SUMMARY

5 REFERENCES



1 AIM OF THE STUDY / MARKET REQUIREMENTS

The fixation of wound dressings, tapes, medical devices and electronics on skin is a challenge requiring the balancing of numerous factors: the necessary adhesion strength, patient comfort, skin integrity and, in the case of wound dressings, ensuring an ideal healing environment.

Gentle silicone gel adhesives have established themselves as the materials of choice in advanced wound care, i.e. for the treatment of chronic wounds, burns, and in post-operative care. The main advantages of silicone gel adhesives are breathability, no allergens, and gentle, atraumatic dressing changes leading to less pain for the patient and faster healing.

Long wear times due to good adhesion may also be a factor for changing dressings less frequently. Wound healing can proceed with less disturbance and the nursing staff has less work to do. This can also reduce treatment costs. Reliable adhesion over a defined period of time is required (from minutes up to days/weeks) when attaching wearable medical electronics or, for instance, stoma systems to the skin.

At the same time, the industry is searching for solutions to avoid skin irritation and damage.

This study shows that foam dressings coated with the high adhesion WACKER silicone gel SILPURAN® 2114 retain an average of more than 90% of their skin adhesion even after seven days' wear time. In comparison, foam dressings coated with the standard adhesive SILPURAN® 2100 had an average remaining adhesion level of 70%.

Laboratory tests support this result, indicating excellent high values for initial tack and adhesive strength for SILPURAN® 2114. The study shows that even the high adhesion SILPURAN® 2114 enables virtually pain-free removal without significant residue.



2 BACKGROUND

Requirements for Wear Time and Adhesion Strength

Field of Application: Advanced Wound Care

The aim is to combine the longest possible adhesion with breathability, atraumatic removal, and the lowest possible skin irritation in the care of chronic wounds, burns, and post-operative wounds (Brown 2014). Only in this way is it possible to create an ideal environment for wound healing, where the wound is not repeatedly subject to stress. This can also reduce treatment costs and save valuable working hours. Less waste is also created – a requirement that is becoming even more significant with regard to sustainability aspects. Outpatient treatment, which requires materials with sufficient adhesive strength, also profits from longer wear times. However, an upper limit of seven days is indicated in this area because there are other factors that limit the wear time, such as wound exudate management or the various phases of wound healing that require different types of dressings.

Field of Application: Tapes and Adhesive Layers For Fixing Medical Equipment and Electronics

The requirements for the adhesive strength are dependent on the wear time and weight of the element to be attached to the skin. Short-term fixing of, for example, electrodes for a few minutes poses different requirements than long-term fixation of a sensor that needs to remain on the skin for up to seven or more days. Repeated long-term use on the same body area, as in blood glucose level monitoring or for stoma care, places a lot of stress on the skin. This is why the providers of blood glucose level monitoring systems are working at great speed to create the most skin-friendly fixation solutions because many patients suffer from skin irritation due to the acrylic-based adhesives currently used (Medicines and Healthcare products Regulatory Agency 2019).

Factors that Influence Wear Time

Patient

There are many factors in relation to patient behaviour that take large influence on the reachable wear times of a dressing such as mobility, type and frequency of showering/bathing and other mechanical stresses in the area of the wound dressing (for instance from clothing or sport).

Characteristics of the Wound or Fixation Environment

The position, size, quantity of wound exudate and the condition of the surrounding skin, amongst other factors, substantially influence the wear time of the dressing.

Properties of the Wound Dressing / Tape

The adhesion to the wound and surrounding skin depends on the surface adhesion level of the adhesive on the skin and/or wound and on how well the dressing/tape adapts to the skin surface structure and movements (conformity).

Ability to retain liquids / absorb wound exudate

A comparative study on the wear time of various foam wound dressings describes the relationship as follows: dressings that cannot retain liquid within their structure may leak under pressure. As soon as the wound environment is moist, adhesion with silicone adhesives is limited due to the hydrophobic properties of the silicone. Dressings with low liquid retention may lead to adhesion problems as they will release more exudate under pressure (Jackson, Lay & Stephenson n.d.).

Skin sensitization and allergic reactions to ingredients in the adhesive materials:

Skin sensitization and allergic reactions can lead to the moisture content of the skin rising and negatively influencing the adhesion strength.

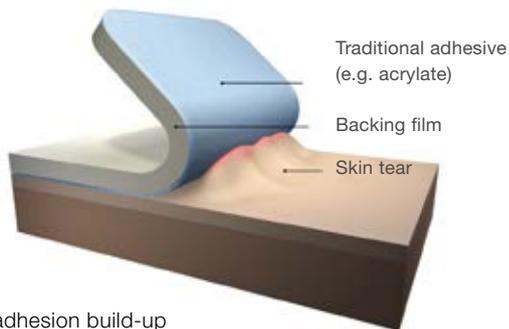
Causes for Adhesion of Silicone Gels

In contrast to traditional skin adhesives, silicone adhesives have a very low surface energy and high elasticity (very low modulus of elasticity). This allows them to rapidly conform to the surface structure of the skin and achieve their maximum adhesion strength from the time of application. As they do not evidence cold flow (Henkel, Stieneker & Wesch, M. 2013), and therefore do not penetrate into finer structures, the adhesion strength does not increase over time. The high elasticity at low force means that the dressing can be removed painlessly and without trauma.

Characteristics of Removal

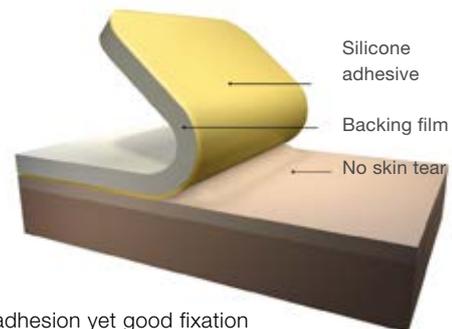
The graphics show how the particular property profile of the silicone gels, with regard to adhesion, softness and flexibility, enable atraumatic removal without damaging epidermal cells. This removal behavior is proven by scientific studies (White 2005, 2008). High adhesion silicone gels such as SILPURAN® 2122 (even higher adhesion than the SILPURAN® 2114 used in this study) also have this advantage.

Trauma Caused by Removal of Conventional Wound Dressing



- High adhesion build-up
- Cell attachment to adhesive
- Skin removal on peel-off
- Severe skin trauma and pain

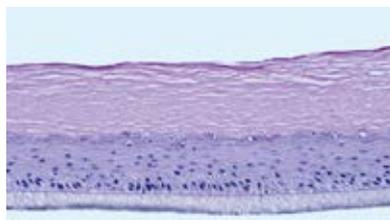
Trauma-free Removal of Wound Dressing with Silicone Adhesive



- Low adhesion yet good fixation
- Repositionable
- No skin stripping or trauma upon removal
- Very sensitive and pain-free removal

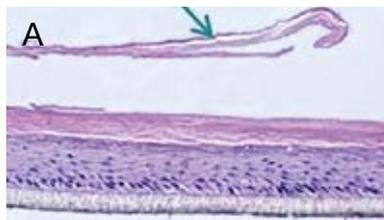
Cell Stripping Test Shows Clear Advantage of Silicone Skin Adhesives

Skin cell layers



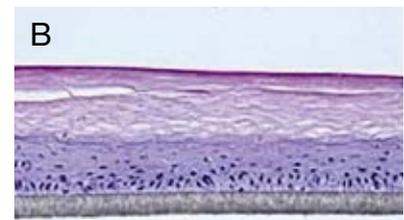
Skin cells before experiment

Cell stripping with acrylic adhesive



Acrylic adhesive
Adhesion strength: 210 N/m

No skin damage with silicone of similar adhesion strength



SILPURAN® 2122
Adhesion strength: 160 N/m

- Cell stripping with acrylic adhesive (A)
- SILPURAN® 2122 (B) similar adhesion strength to acrylic adhesive but no cell stripping



3 STANDARD VS HIGH ADHESION SILICONE GELS

Evaluation of Wear Time, Repositioning, Pain and Residues

3.1 Method / Study Design

The following study design was chosen to evaluate wear time, pain, residue and repositionability of standard versus high adhesion silicone gels:

- Study with fifteen volunteers; sociodemographic data were not recorded
- Self-evaluation of three aspects:
 - Level of pain on removal
 - Wear time (with and without repositioning, maximum seven days)
 - Residue on the skin
- No restrictions with regard to sports activities or body care, documentation of showering/bathing, sweat-inducing sports activities and other particular stresses
- Study carried out with foam dressings, coated with SILPURAN® 2100 and SILPURAN® 2114 (7.5 x 7.5 cm, perforated, surface weight of the coating 150 g/m², perforation diameter 4 mm)



Table 1: The Two SILPURAN® Adhesives Used in the Study

Product	Viscosity A [mPa s]	Viscosity B [mPa s]	Penetration* [1/10mm]	Peel** [N/m]	Tack** [N]	Pot life 23°C [min]
SILPURAN® 2100	34,000	35,500	205	110	54	73
SILPURAN® 2114	12,000	10,000	200	140	66	70

For standard specifications and technical parameters, refer to the technical data sheet. *hollow cone 62.5 g, 60 sec.

** On stainless steel

3.2 Study Results

Pain perception: after 5 minutes and after 6 hours

The wound dressings coated with the comparison products were applied two at a time to the forearm. Two dressings were removed after 5 minutes and the pain perception level was rated. Two further dressings were removed after 6 hours and the pain perception level was rated according to the Wong-Baker FACES scale (Wong-Baker FACES Foundation 2018).

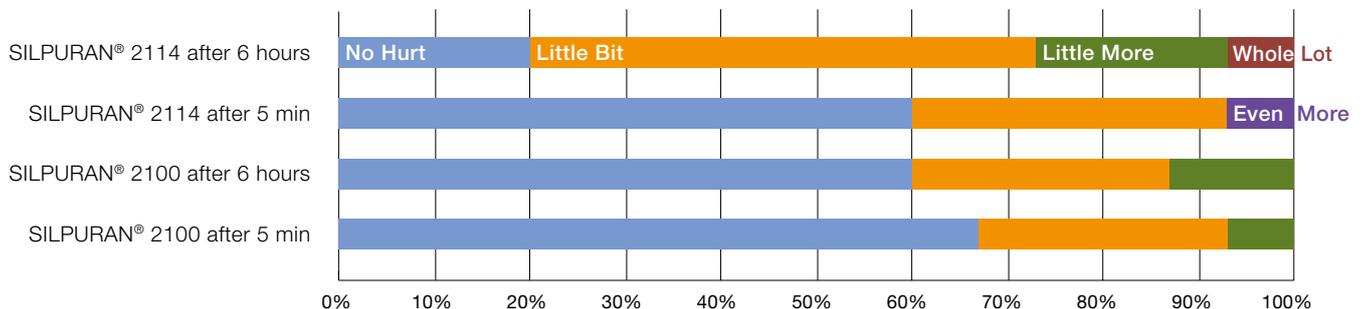


97% of the study participants rated the pain as not present (52%) or minor (45%). The majority of participants said that they required more force and perceived a little more pain when removing the dressings with SILPURAN® 2114, the gel with the greater adhesion strength, after 6 hours wear time.

This study only used silicone-coated dressings whereby the pain reference was set very low. In a comparative study with acrylate-based adhesives, we would expect an even lower relative pain perception for the silicone-coated dressings. (Schweigel, Witte & Dybe 2020).

Pain: Ø 97% of Removals Painless / Little Pain

Dressings coated with SILPURAN® 2100 and 2114 were applied to the forearm and pain was rated (acc. to Wong-Baker FACES® Pain Rating Scale) on removal after 5 minutes and after 6 hours.



Pain perception reference = soft silicone gels only
52% of removals = painless, 97% of removals = painless / little hurt
Higher tack gel SILPURAN® 2114 perceived little more painful / slightly more difficult to remove.

Wear time of SILPURAN® 2100 compared to SILPURAN® 2114

Wound dressings coated with the comparison products were attached to 3 different body parts (forearm, calf, lower back) and daily checks were made regarding possible detachment. Any dressings that had not detached by themselves were removed after 7 days as maximum observation period.

Participants documented average daily water contact of 75%, including showering, bathing, swimming and sweat-inducing sport.

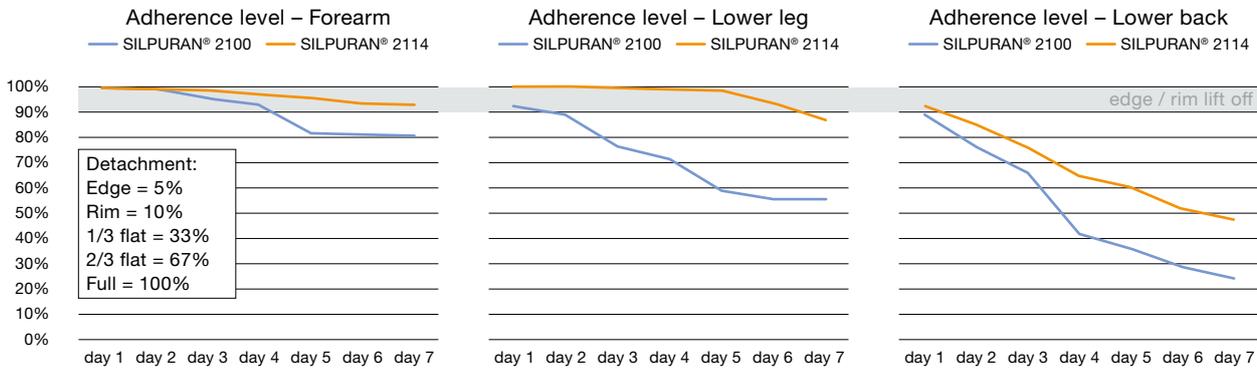
After 7 days of wear, the dressings coated with the highly adhesive SILPURAN® 2114 and applied to the forearm and calf evidenced an average surface adhesion level of 90%, compared

to 70% for the dressings coated with SILPURAN® 2100. The surface adhesion level was calculated using a standard scaling assigning 5 possible values to the different detachment levels: edge lift-offs were calculated as 5% detachment, rim lift-offs with 10%, 1/3 flat detachments with 33%, 2/3 flat detachments with 67% and full detachments with 100%.

The wear time of the dressings on the lower back was significantly lower, as frequent mechanical stress on this part of the body from clothing (waistbands) or sports equipment (e.g. foam roller) led to earlier detachment of the dressings. In patient care, usually a dressing with a larger surface area would be used on this part of the body compared to the dressing size used in this study.

Wear Time: 90 % Adherence of SILPURAN® 2114 Dressings after 7 Days (Leg/Forearm)

Dressings coated with SILPURAN® 2100 + 2114 were applied to the forearm, lower back + lower leg (total 6 dressings per participant). Any detachments were documented daily.



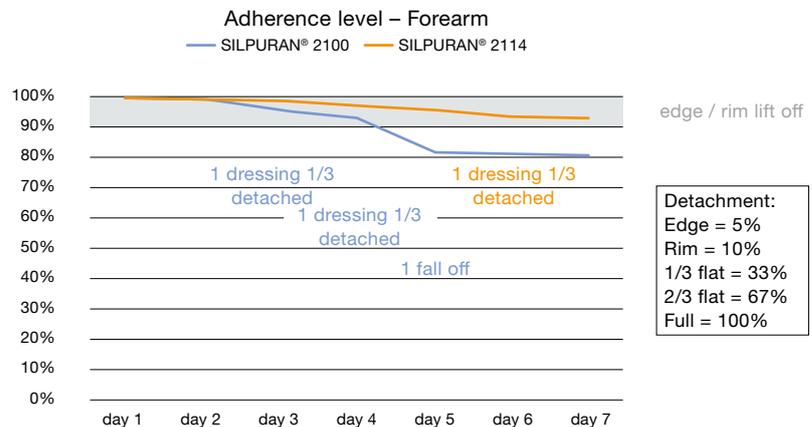
Dressings on the lower back showed faster detachment due to mechanical stress from clothes, sports equipment and consequent water uptake of the foam layer.

The forearm dressings coated with SILPURAN® 2114 had an average adhesion level of 93% after 7 days wear time, compared to 80% for SILPURAN® 2100.

The forearm dressings coated with SILPURAN® 2114 only had minor edge and corner detachments after 7 days wear time. In one case only, a surface detachment of approximately 1/3 of the surface area was documented. All dressings therefore achieved the 7 day wear time on the forearm.

Wear Time: 93% Adherence of SILPURAN® 2114 Dressings after 7 Days (Forearm)

Both silicone adhesive gels show an excellent adhesion level over the whole 7 day study period.

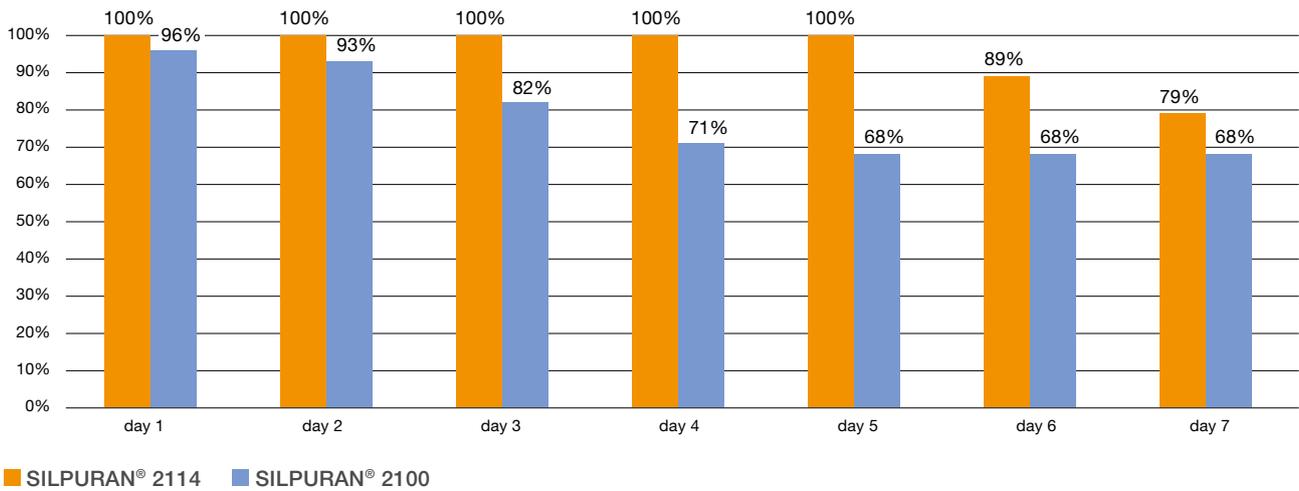


The higher peel adhesion and tack values of SILPURAN® 2114 versus SILPURAN® 2100 are manifested in higher surface adhesion level and wear time.

In this study, the forearm and calf dressings coated with SILPURAN® 2114 showed excellent adhesion quality – surface detachments of the dressings were only seen from the 6th day, before that time, only minor edge and rim detachments were

documented. Surface detachments were noted at an earlier stage for the SILPURAN® 2100 with the standard adhesion values. However, the dressing percentage without surface detachment stabilized from day 4 at a very high level (approx. 70%).

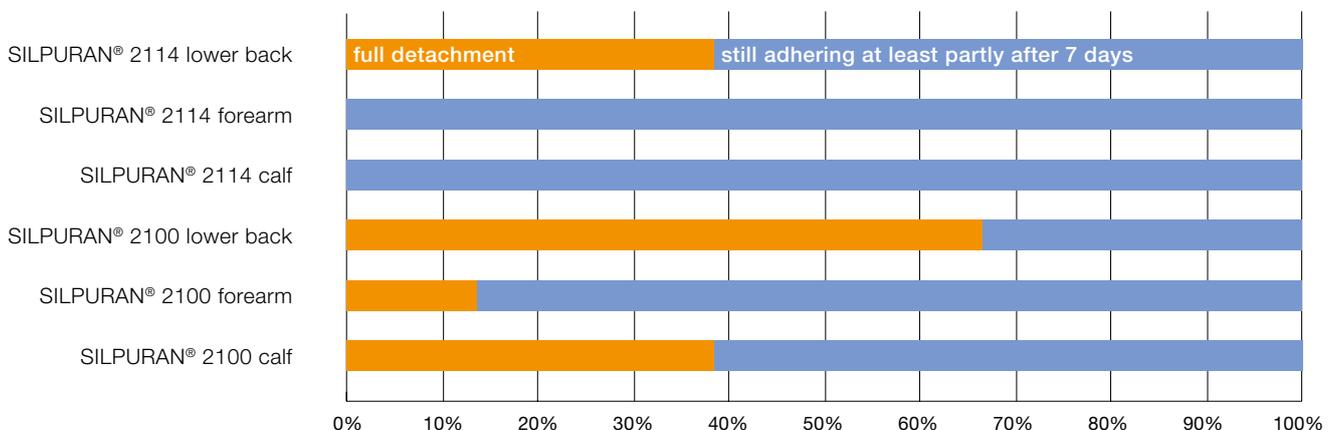
Forearm + Lower Leg Detail Adhesion: Percentage of Dressings with Full Adhesion (Incl Rim /Edge Lift-off)



There was no complete detachment on the forearm/calf over the 7 day period of the dressings coated with SILPURAN® 2114, while 25% of the dressings coated with SILPURAN® 2100 detached completely during the

7 day period. It was noted that it is important to correctly apply the dressings at the start. As soon as water penetrates the foam layer, the adhesion of the hydrophobic silicone gel layer is affected.

0% of SILPURAN® 2114 Dressings Detached Completely (Forearm / Calf) Versus 25% for SILPURAN® 2100



Correct initial positioning proved important. Once water got into the foam layer of the dressing, adhesion became difficult. With an average value of 76% daily shower / bath / intense sweating of participants, the dressings proved to have excellent adhesion overall. Dressings on the lower back showed faster detachment due to mechanical stress from clothes, sports equipment and consequent water uptake of the foam layer.

Documentation sheet: Wear Time – Day 1						
	Calf		Lower back		Forearm	
SILPURAN	2100	2114	2100	2114	2100	2114
Complete adhesion	<input type="checkbox"/> yes	<input type="checkbox"/> yes	<input type="checkbox"/> yes	<input type="checkbox"/> yes	<input type="checkbox"/> yes	<input type="checkbox"/> yes
Edge / rim detachment (mark position(s) with a circle)						
Flat detachment	<input type="checkbox"/> ~1/3	<input type="checkbox"/> ~1/3	<input type="checkbox"/> ~1/3	<input type="checkbox"/> ~1/3	<input type="checkbox"/> ~1/3	<input type="checkbox"/> ~1/3
	<input type="checkbox"/> ~2/3	<input type="checkbox"/> ~2/3	<input type="checkbox"/> ~2/3	<input type="checkbox"/> ~2/3	<input type="checkbox"/> ~2/3	<input type="checkbox"/> ~2/3
	<input type="checkbox"/> full	<input type="checkbox"/> full	<input type="checkbox"/> full	<input type="checkbox"/> full	<input type="checkbox"/> full	<input type="checkbox"/> full
Activity / water contact	<input type="checkbox"/> Shower <input type="checkbox"/> Sweat intense sports <input type="checkbox"/> Bath / Swimming <input type="checkbox"/> Other special strain: _____					

Wear time after repositioning

One subgroup had their dressing coated with SILPURAN® 2114 removed after the initial application and repositioned in a different place.

The results did not show any significant deviation from the possible wear time compared to the dressings that were not repositioned.

Residue on the skin

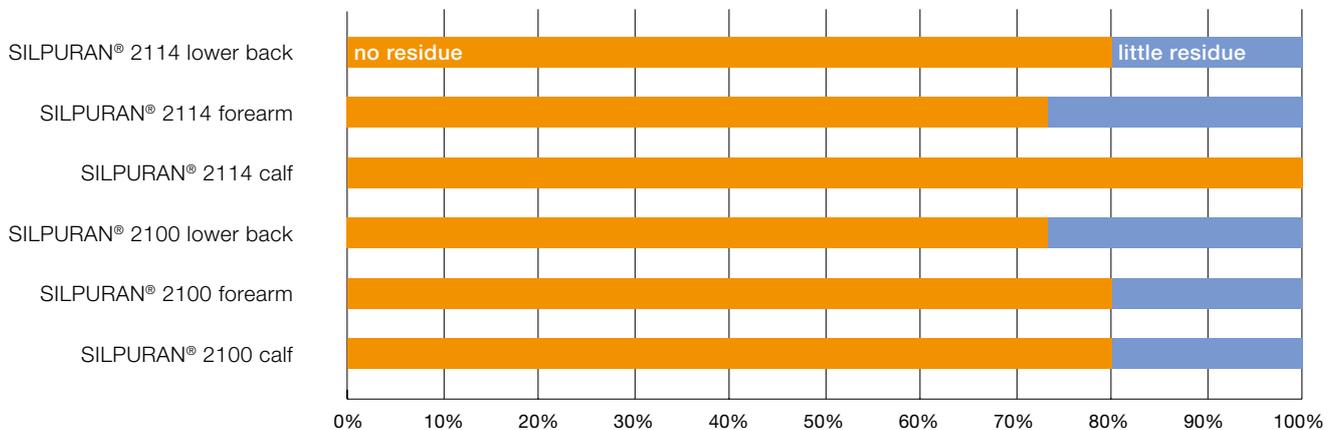
The previously covered skin areas were evaluated after complete removal (passive or active) with regard to adhesion and adhesive residue on the skin.

No or only minimum adhesive residue were documented on the skin in 100% of the cases.

Residue after Detachment						
	Calf		Lower back		Forearm	
SILPURAN	2100	2114	2100	2114	2100	2114
Residue on skin after detachment:	<input type="checkbox"/> none					
	<input type="checkbox"/> little					
	<input type="checkbox"/> a lot					

Residue: 100% with No or Only Little Residue, 81% Cases without Residue

Dressings coated with SILPURAN® 2100 and 2114 were applied to the forearm.
Adhesive residue were rated after full detachment (max. 7 days wear time): none, little, a lot

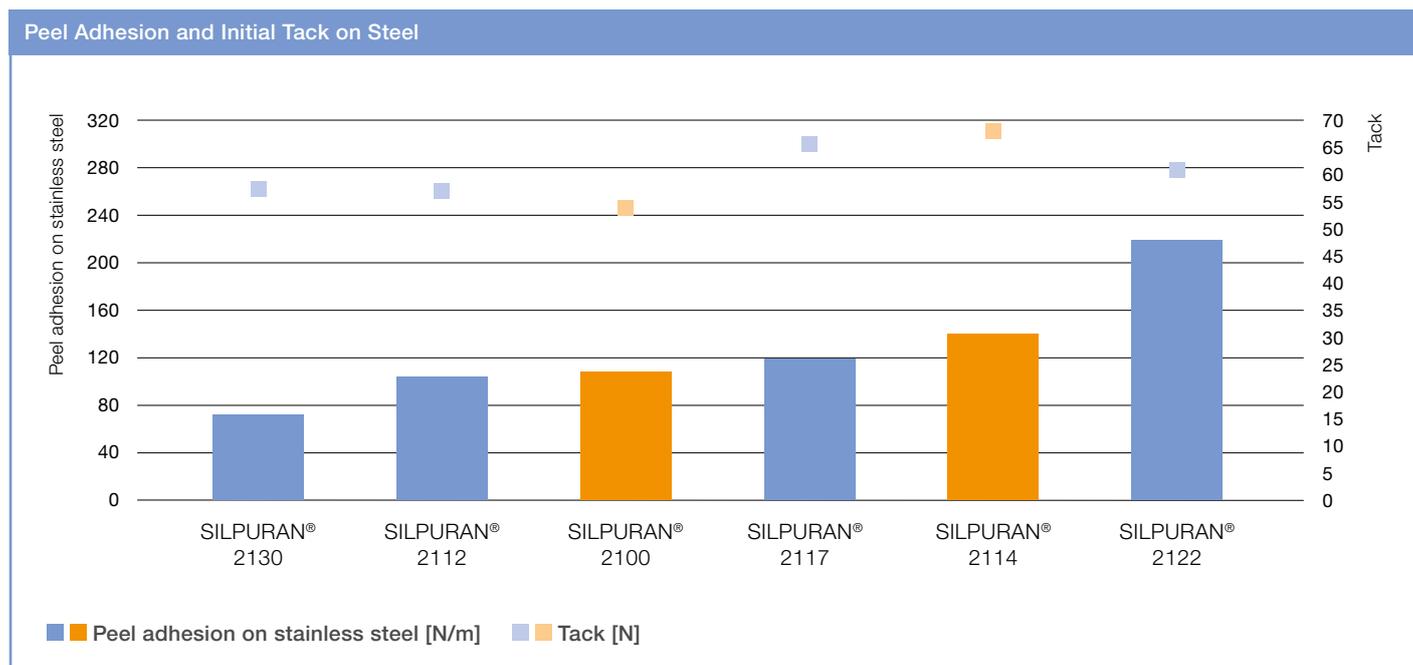


Residue became apparent where the dressing was no longer completely attached (dirt / water catch).

3.3 Supplementary Laboratory Results

SILPURAN® silicone gel adhesives are available in a wide range of initial tack and adhesion strength levels.

The following graphic shows peel adhesion and initial tack values measured on steel.



These data are determined with the following measurement methods for silicone gel adhesives:

Peel Adhesion and Tack Measurements for SILPURAN® Skin Adhesives

Peel test

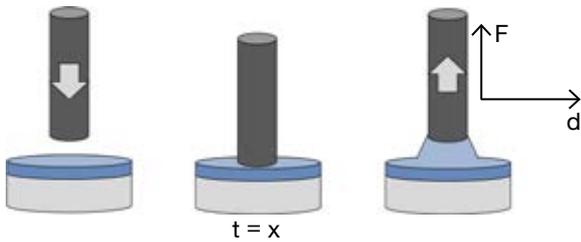
- Determines adhesion strength and tear strength of a material
- Expressed as force that is needed to tear a strip of tape constantly from a test platen
- Measurement on stainless steel and human skin (forearm)

Tack measurement

- Determines the force needed to separate an adhesive from the test specimen after short period of time
- Expressed as maximal tearing force F_N

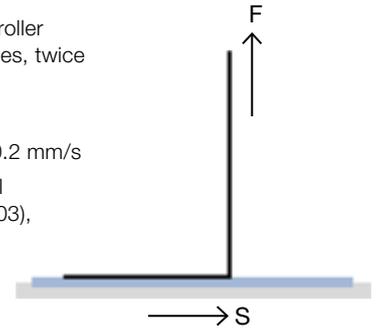
Technical Parameters for Tack Measurement

- 100 µm adhesive layer
- Substrate: stainless steel
- Expressed as maximal tearing force FMAX
- Dwell time: 10 min
- Contact pressure: 1.5 N
- Measurement speed: 2 mm/sec



Technical Parameters for 90° Peel Release Force Measurements

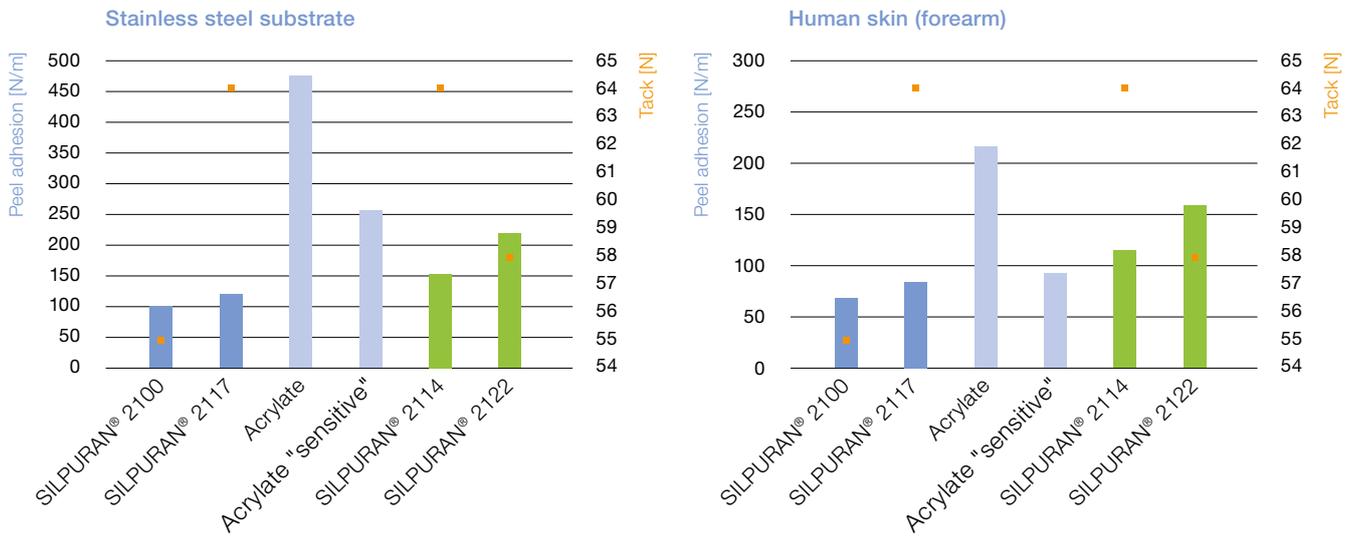
- Following EN 1939:2003/ASTM D3330/D3330M
- Size of test stripes: 2.5 cm x 12-5 cm
- 100 µm adhesive layer
- 50 µm PU-film (Epurex®)
- Rigid fixation material
- Application weight: hand roller
2 kg roller passes: 4 passes, twice in each direction
- Dwell time: 30 min
- Test speed: 5.0 mm/s ± 0.2 mm/s
- Substrates: stainless steel (according to EN1939:2003), human skin (forearm)



Internal tests at WACKER show excellent adhesion values for the high adhesion strength silicone gel adhesives in

comparison to selected acrylics when measured on skin.

New Skin Adhesives Show Strong Improvement of Adhesion Properties



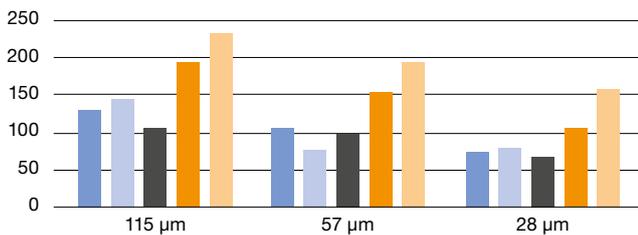
New SILPURAN® grades close the gap between the current silicone adhesive portfolio and other technologies (e.g. acrylate adhesives).

The adhesion strength is dependent on the coating thickness. Adhesion values that are only reached by standard gels when they have a double coating thickness are achieved by high

adhesion silicone gel adhesive such as SILPURAN® 2114 with a reduced layer thickness of ~50 µm or less.

Lower Coat Weight Makes Applications Accessible where Silicones were not Feasible in the Past

Peel adhesion on steel [cN/cm]



Adhesive layer thickness (=coating weight)

- SILPURAN® 2100
 - SILPURAN® 2112
 - SILPURAN® 2117
 - SILPURAN® 2114
 - SILPURAN® 2122
- existing grades
- NEW

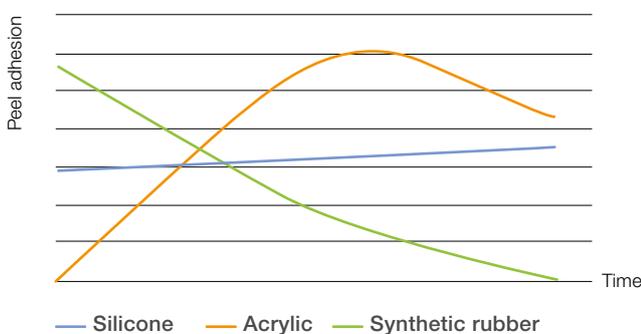
- Possible silicone coating thickness ~ 50 µm or below (currently ~ 150 µm)
- Silicone will bring benefits to the applications in question
 - no allergies
 - high breathability
 - less pain on removal

Product	Penetration [1/10]	Peel adhesion steel [N/m]		
		115 µm	57 µm	28 µm
SILPURAN® 2100	208	132	105	74
SILPURAN® 2112	232	145	76	81
SILPURAN® 2117	219	105	99	68
SILPURAN® 2114	211	195	154	104
SILPURAN® 2122	200	233	193	159

As repositioning, when applying dressings or sensors, is desired in everyday care and in care homes, SILPURAN® 2100 was tested for this capability in the laboratory. Additional values remain constant over time even after dressings have

been peeled off and repositioned. The graphic shows the behavior of silicone gels in comparison to acrylate or synthetic rubber-based adhesives.

Repeated Peel-off Simulates Repositioning of a Dressing – Strong even on Second Peel-off



Peel adhesion [N/m]	SILPURAN® 2100
first peel after 10 min	Steel: 46 Skin: 51
second peel after 30 min	Steel: 42 Skin: 52
second peel after 60 min	Steel: 43 Skin: 64

- Overall high adhesion strength even at second peel-off
- Constant adhesion after repositioning
- Constant long term adhesion of silicone gels



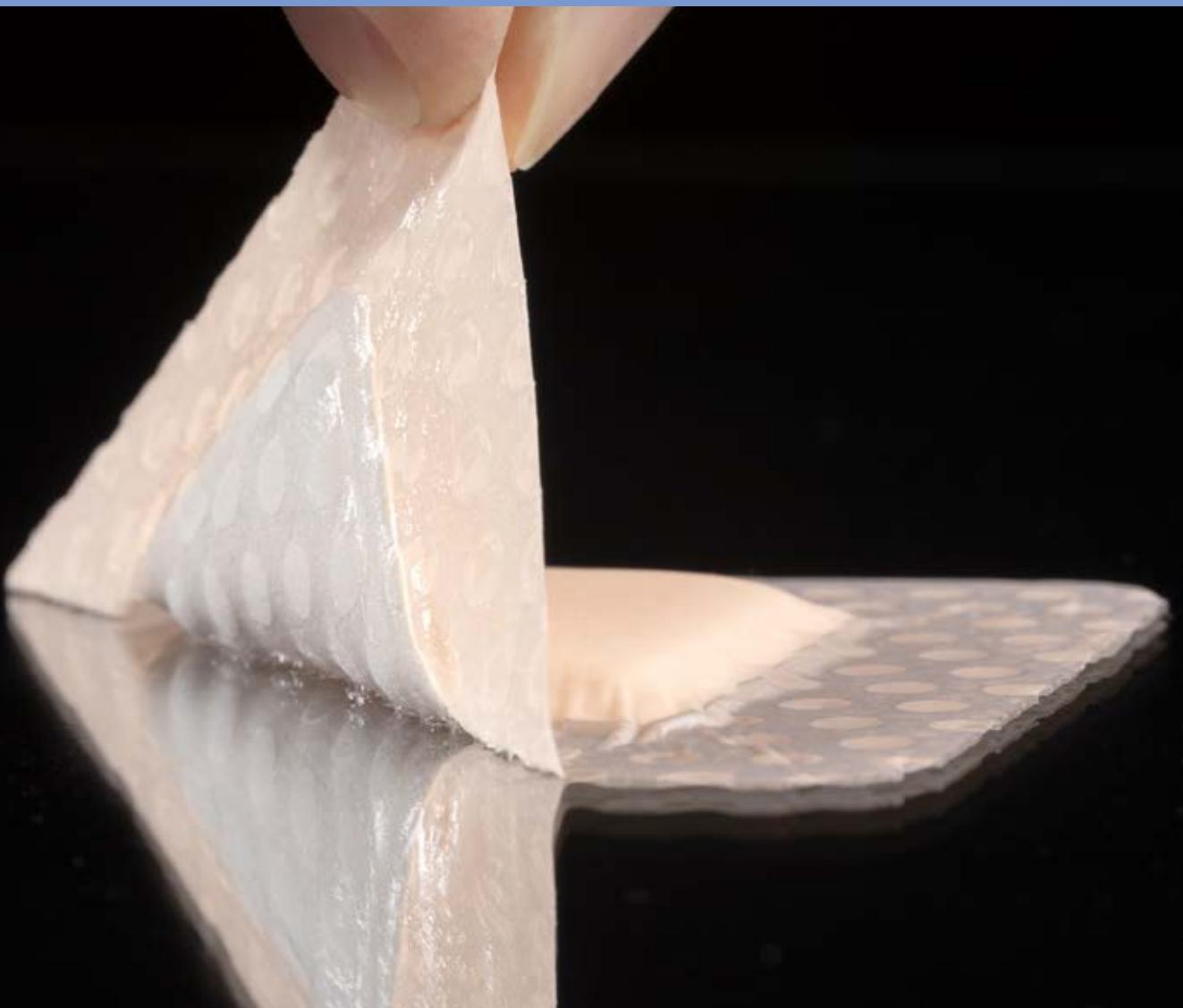
4 SUMMARY

The dressing wear times reached in the study for both adhesives meet the requirements for the treatment of chronic wounds and enable a low frequency of dressing changes. The high adhesion silicone gel SILPURAN® 2114 shows an improved level of adherence compared to the standard product SILPURAN® 2100, allowing even longer wear times. No restrictions in patient mobility were noted, very good wear times were reached, even at a high level of sports activity and frequent showering.

The study confirmed the known advantages of silicone adhesives with regard to removal without leaving a residue and no or little pain perception during removal.

The greater adhesion strength of SILPURAN® 2114 can make lower coating thicknesses possible, which, in turn, enable a wider application range for silicone adhesive gels from an economic point of view. Tapes can also be produced that are tactilely comfortable, thin and very flexible, i.e. ideal for particularly fragile skin in the sector of premature babies and intensive child medicine.

SILPURAN® 2114 narrows the gap with regard to the achievable wear times, between standard silicone adhesive gels and acrylic-based skin adhesives. This means that more patients and users will be able to profit from the skin-friendly and supportive wound healing properties of silicone gels in the future. SILPURAN® 2114 is a solution for skin fixation products requiring strong and constant adhesion as well as no skin irritation and damage.



5 REFERENCES

- Brown, A. (2014). Strategies to reduce or eliminate wound pain. *Nursing Times*, Volume 110 (15), pp. 12–15. Available at: <https://www.nursingtimes.net/clinical-archive/tissue-viability/strategies-to-reduce-or-eliminate-wound-pain-04-04-2014/>.
- Henkel, G., Stieneker, F. and Wesch, M. (2013). *Lexikon der Pharmatechnologie*. Available at: <https://prozesstechnik.industrie.de/pharma/lexikon-pharmatechnologie/kaltfliessen/>.
- Jackson, S., Lay, S., and Stephenson, C. (no date). A Comparison of the Wear Time of Dressings with Silicone Adhesives. [Poster]. Crawford Healthcare, King Edward Court, King Edward Road, Knutsford, Cheshire, UK.heshire, UK
- Medicines and Healthcare products Regulatory Agency. (2019). Alert to users of FreeStyle Libre flash glucose monitoring system regarding skin reactions to sensor adhesive. [Press release]. Available at: <https://www.gov.uk/government/news/alert-to-users-of-freestyle-libre-flash-glucose-monitoring-system-regarding-skin-reactions-to-sensor-adhesive>.
- Schweigel, H., Witte, C. and Dybe, V. (2020). 'Assessment of pain reduction and skin damage for newly developed silicone-based adhesive fixation products* in healthy human subjects.' EWMA 2020. Virtual conference. 18–19 November 2020. Available at: <https://ewma.conference2web.com/#resources/assessment-of-pain-reduction-and-skin-damage-for-newly-developed-silicone-based-adhesive-fixation-products-in-healthy-human-subjects-c39e0e34-1d2e-4f2a-92b7-0e2b7f80f528>.
- White, R. (2005). Evidence for atraumatic soft silicone dressing use. *Wounds UK*, Volume 1, pp. 104–109. Available at: https://www.researchgate.net/publication/237641992_Evidence_for_atraumatic_soft_silicone_dressing_use.
- White, R. (2008). A multinational survey of the assessment of pain when removing dressings. *Wounds UK*, Volume 4 (1), pp. 14–22. Available at: https://www.researchgate.net/publication/265205162_A_multinational_survey_of_the_assessment_of_pain_when_removing_dressings.
- Wong-Baker FACES Foundation. (2018). Wong-Baker FACES® Pain Rating Scale. Used with permission from <http://www.WongBakerFACES.org>.

Further Study Regarding the Topic of Wear Time with Silicone Gel Adhesives

- Rippon, M., Waring, M. and Bielefeldt, S. (2015). An evaluation of properties related to wear time of four dressings during a five-day period. *Wounds UK*, Volume 11(1), pp. 45–54.5



WACKER

Wacker Chemie AG
Hanns-Seidel-Platz 4
81737 Munich, Germany
www.wacker.com/contact

www.wacker.com

Follow us on:



The data presented in this medium are in accordance with the present state of our knowledge but do not absolve the user from carefully checking all supplies immediately on receipt. We reserve the right to alter product constants within the scope of technical progress or new developments. The recommendations made in this medium should be checked by preliminary trials because of conditions during processing over which we have no control, especially where other companies' raw materials are also being used. The information provided by us does not absolve the user from the obligation of investigating the possibility of infringement of third parties' rights and, if necessary, clarifying the position. Recommendations for use do not constitute a warranty, either express or implied, of the fitness or suitability of the product for a particular purpose.