Selecting the right medical adhesive tape

Challenges facing the medical device designer

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Introduction

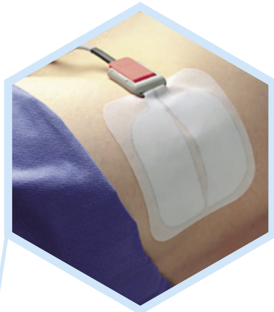
Medical-grade pressure sensitive adhesives (PSAs) are generally easy to handle and process and are used widely in all areas of health care[1]. Since their introduction, medical-grade PSAs have been coated on a variety of backings to form medical tapes, which are currently used in a vast number of applications[2].

Typical applications for single-coated tapes include wound care dressings, surgical tapes and electrodes, while double coated tapes and transfer adhesives are regular components of medical devices, such as diagnostic test strips, ostomy devices, surgical drapes, advanced wound care dressings and other point-of-care applications.

Selecting the right adhesive is critical to the success of a new device, as this can seriously affect the device's performance, as well as the ease of its manufacture. Furthermore, the choice of backing for an adhesive can have a major impact on the wear time and comfort of a medical device.

A common approach is to choose an adhesive and backing based on information supplied on a manufacturer's product data sheets. However, the data in manufacturers' data sheets may have been generated using a variety of different methods. A meaningful comparison of test data for adhesive tapes from different manufacturers therefore remains questionable.

This paper seeks to shed some light on how comparable such data are, and how relevant they may be for the performance of the PSA tape in a specific application.



1. McNichol, L., Lund, C., Rosen, T., Gray, M., Medical Adhesives and Patient Safety: State of the Science, J WOCN, July/August 2013, pp 365-380.
2. Tsaur, A.T., Tsaur, T., PSTC publications, http://www.pstc.org/i4a/pages/index.cfm?pageID=4417

Why use a medical-grade PSA?

Introduction of a medical device to the market is dependent on approval from a Notified Body, an organisation approved by a competent authority to assess manufacturers' compliance with the medical device directive. The competent authority is appointed by the national government to enforce compliance with the medical device directive in that country. For the UK the competent authority for the medical device directive is the Medicines and Healthcare products Regulatory Agency (MHRA).

Regulators only consider the biocompatibility of the finished medical device in its entirety, not its individual components. However, by selecting input materials known to be biocompatible, it is more likely that the final medical device will successfully pass biocompatibility evaluation.

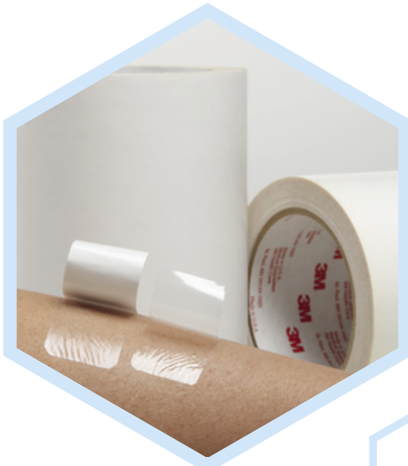
Suppliers of medical-grade PSAs generally manufacture their products in line with ISO 9000 quality management standard requirements as a minimum. Furthermore, adhesives classed as medical grade have normally undergone biocompatibility testing.

The tests for biocompatibility are covered in the ISO 10993 standard, Biological Evaluation of Medical Devices. Cytotoxicity and MEM elution to ISO 10993-5 are in vitro tests, which assess the toxic effects of adhesive extracts on cell cultures.

Primary skin irritation and sensitisation to ISO 10993-10 are in vivo tests, which evaluate the irritation potential of the adhesive formulation, and mechanical trauma of removing the adhesive from skin.

For stick-to-skin applications, an additional claim of hypoallergenic properties may be considered. A hypoallergenic claim is commonly supported by results of a repeat insult patch test. This involves the repeat application of samples on healthy volunteers for a two-to-three week period, followed by a two-week rest period, and a challenge application. To be termed hypoallergenic, the adhesive product must show no evidence of sensitisation potential under these test conditions.

By selecting biocompatible and in stick-to-skin devices, hypoallergenic adhesive tapes for incorporation into their products, medical device manufacturers act pre-emptively and increase the chance for successful product audit and approval.



What Adhesives are available?

There are several different types of medical-grade PSAs available today. The most common are synthetic rubber, acrylate and silicone adhesives, all of which have their own advantages and disadvantages. In addition, soft silicone gel adhesives have been introduced to the market for stick-to-skin applications. In order to compare them, it is necessary to define the relevant performance parameters.

A PSA's performance is often defined in terms of tack, adhesion to steel and shear strength:

- **Tack** describes a PSA's ability to rapidly form a bond with the substrate and resist debonding[3].
- **Adhesion to steel** describes the resistance of the adhesive to a 90 degree or 180 degree peel from a steel surface. The peel surface is specified in terms of the type of material and its surface roughness[4].
- **Shear strength** is most commonly measured by attaching a static load to ascertain how resistant the adhesive is to forces working parallel to the adherent surface, effectively peel forces at 0 degree peel angle. The shear strength of an adhesive is closely linked to its cohesive strength and creep behaviour.

Synthetic Rubber Adhesives

Synthetic rubber adhesives are strong, show high peel adhesion values, but are not breathable. They are also likely to leave adhesive residue when peeled (see **Figure 1**).

For these reasons, it is not advisable to choose a rubber adhesive for stick-to-skin applications where a long wear time or repeated application of adhesive to the same part of the body is expected. Also it is not recommended to use rubber-based PSAs on parts of the body where the skin is more sensitive e.g. eyelids.

Figure 1: Tape with rubber-based PSA being removed. The red areas are caused by skin trauma on removal of the adhesive.

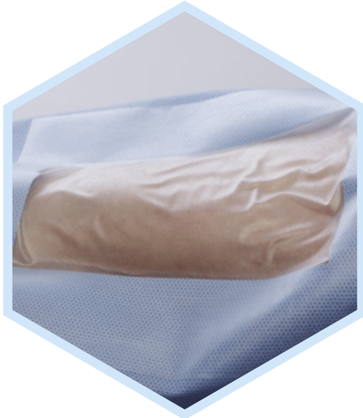
3. Yarusso, D., Chapter 13, Effect of rheology on PSA performance in Adhesion Science and Engineering, vol. I: The Mechanics of Adhesion, Dillar D.A., and Pocius A.V., Elsevier, Amsterdam cap. 6, 2002.
4. American Society for Testing and Materials, D3330/D3330M-04.

Acrylate Adhesives

Acrylate adhesives can be designed with high or low tack, and high or low peel strength. The tack properties of the formulation can be influenced by the addition of tackyfiers, however these can change the overall rheology of the PSA and may reduce its cohesive strength. The peel adhesion strength of acrylate PSAs can also be influenced by the PSA formulation.

Acrylate PSAs are permeable to water vapour. The degree of moisture permeability, measured by the moisture vapour transmission rate (MVTR) varies with the thickness of the adhesive coating and the adhesive formulation. Most acrylate adhesives release cleanly off substrate surfaces without leaving adhesive residue.

The fact that tack and adhesion can be finely tuned, and that the adhesives are breathable, makes acrylate adhesives more suitable for stick-to-skin applications than synthetic rubber adhesives.



Silicone PSAs and Soft Silicone Gel Adhesives

Silicone PSAs perform exceptionally well on low surface energy substrates. The adhesive formulation can be adjusted to high or low tack, and high or low peel adhesion.

Over the last few years, soft silicone gel adhesives have been established in the stick-to-skin market for medical devices. Soft Silicone Gel adhesives exhibit a significantly lower peel adhesion than the synthetic rubber and acrylate PSAs, resulting in less skin trauma on removal[5].

They are particularly useful when an adhesive has to be used on fragile skin like that of babies, the elderly or patients with co-morbidities causing the skin to be more fragile. These very gentle adhesives are also useful for repeat application to the same area of the skin, or where repositioning of the medical device is desirable. A combination of soft silicone gel adhesive and acrylate adhesive in a double coated tape is especially useful for device, sensor and multi-layered dressing construction.

There is no ‘one-size-fits-all’ adhesive, and the most appropriate adhesive tape will be determined by the critical performance criteria for the application. When it comes to stick-to-skin applications, the type of adhesive is also determined by skin condition and wear-time.

5. Waring, M., et al: An evaluation of the skin stripping of wound dressing adhesives, Journal of Wound Care, Sept 2011, Vol.20, No.9, p.412.

Summary Table of Medical Grade Adhesives			
Feature	**Synthetic Rubber**	**Acrylate**	**Soft Silicone Gel**
Peel Adhesion	High	Low to high	Low to medium
Sterilisation Compatibility	EtO, Gamma, Steam	EtO, Gamma, Steam	EtO
Breathability	Low	Tuneable	Medium
Repositionability	×	×	✓
Initial Tack	Good	Low to high	Good
Skin Trauma on Removal	High	Medium	Low

Table 1: Summary table of the features of synthetic rubber PSA, acrylate PSA and soft silicone adhesive gel.

Figure 2 demonstrates the change in peel adhesion to skin over time for three types of adhesive. The silicone gel adhesive only shows very small changes in peel adhesion over time. The adhesive wets out immediately on application and due to its breathability it does not lose adhesion either.

On the other hand synthetic rubber adhesive, whilst demonstrating high initial tack, loses adhesion to skin over time due to the fact that it is not breathable.

Acrylate adhesives are very effective on skin. They enable long wear time whilst maintaining good skin condition due to their breathability. The adhesion increases over time due to the combination of residual cold flow and the uneven surface of the skin.

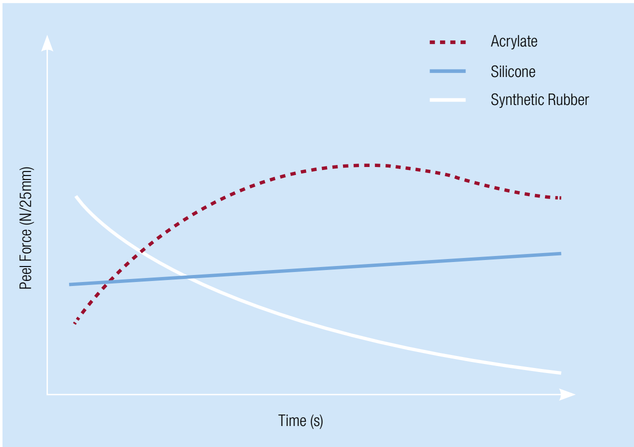
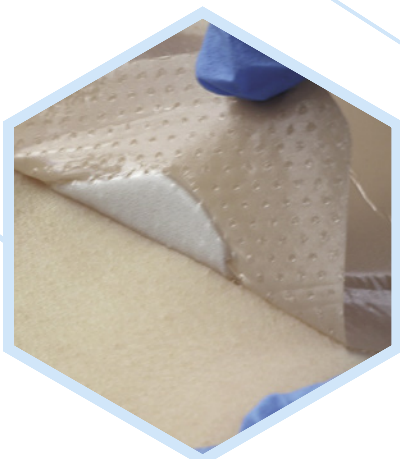


Figure 2: Peel force over time for skin adhesion measurements for synthetic rubber PSA, acrylate PSA and soft silicone adhesive, based on 3M data on file.



Tape Backings and Carriers

The properties of tape backings have an impact on the performance of the adhesive and the assembled medical devices.

For medical device design, the stiffness of a backing can influence how well an adhesive resists the peel forces the adhesive bond is exposed to. For example, stiff polyester film backing can support the adhesive in resisting peel forces.

For most stick-to-skin applications, the tape backing is required to flex with the body's movement. Not all tape backings conform to body contours or body movement.

Backings range from paper and woven cloth to non-woven polyesters, foams and polymeric films, such as polyurethane, polyethylene and polyester. The most appropriate backing is determined by the application requirements.

A simple paper backing is very good for applications such as fixation of tubes or simple dressings. Medical paper tapes can be wound on an easy-to-carry small roll, and strips can be torn off without the need for scissors.

Woven or non-woven backings are strong and breathable. Film backings are waterproof, but not all film backings are permeable to moisture vapour. For most stick-to-skin applications, it is preferable to use a backing with an MVTR at least similar to that of healthy skin (~ 400 g/m^2*24h). Polyurethane films do perform very well in applications where both high MVTR and conformability are required.

When comparing the relative performance of adhesive tapes, device designers are faced with differences in adhesion-to-steel values, due to varying conformability of the backings. A true comparison of peel force of different adhesives is only possible when the same backing is used for all adhesives tested[6].

Summary Table of Medical Tape Backings								
Feature	Filmic			Non-Woven			Woven	Foam
	PET	PE	PU	PET	PU	Cellulose	Cotton Blends	PE/PVC
Conformability	Low	Medium	High	High	High	Medium	High	High
Elongation	×	Medium	High	×	High	Low	Medium	Medium
Tear-ability	×	×	×	×	✓	✓	✓	×
Porosity	×	×	×	✓	✓	✓	✓	×
MVTR	×	Low	High	High	High	High	High	×
Fluid Resistance	✓	✓	✓	×	×	×	×	✓

Table 2: Summary of the features of medical tape backings.

6. Handbook of Adhesive Technology, Second Edition, Chapter 12 The Physical Testing of Pressure-Sensitive Adhesive Systems, John Johnston, Consultant, Charlotte, North Carolina, U.S.A..

Figure 3 shows the impact a difference in backing conformability can have on the peel adhesion values for a given PSA. The impact of backing stiffness on peel adhesion illustrates how difficult it can be to compare adhesive performance data from data sheets.

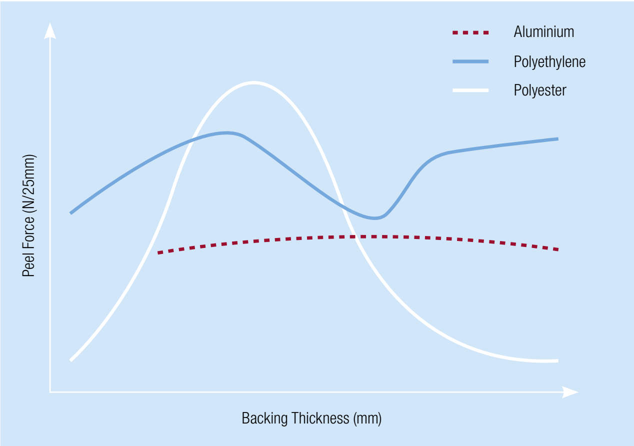


Figure 3: Impact of backing thickness on peel adhesion values, based on source 4 Handbook of Adhesive Technology, Second Edition, Chapter 12 The Physical Testing of Pressure-Sensitive Adhesive Systems, John Johnston, Consultant, Charlotte, North Carolina, U.S.A.

Comparing performance data

Adhesion.

As mentioned previously the performance of PSAs is most commonly characterised by the three parameters: tack, peel and shear.

Tack describes the ability of a PSA to rapidly form a bond with the substrate and resist debonding[7]. Peel adhesion, often expressed as adhesion to steel, describes the resistance of the adhesive to a 90 degree or 180 degree peel from a steel surface. The shear strength of an adhesive is a measure of how resistant the adhesive is to shear stresses or peel forces at 0 degree peel angle.

Table 3 summarises the most commonly used standard methods to generate data to assess the tack, peel and shear strength of a PSA.

Methods to measure adhesive properties				
		ASTM	**ISO**	**PSTC**
Tack	Loop	D6195-03	EN 1719	PSTC-16
	Rolling Ball	D3121-06	EN 1721	PSTC-6
	Probe	D2979-01	×	×
Peel	180°	D3330/D3330M-04	EN 1939	PSTC-101
	90°	D3330/D3330M-04	EN 1939	PSTC-101
	T-test	D1876-08	11339	×
Shear	Static	D3654	EN 1943	PSTC-107
	Dynamic	×	4587	×

Table 3: Some standard methods to assess pressure sensitive adhesive performance.
ASTM: American Society for Testing and Materials, ISO: International Organisation for Standardisation, PSTS: Pressure Sensitive Tape Council.

7. Yarusso, D., Chapter 13, Effect of rheology on PSA performance in Adhesion Science and Engineering, vol. I: The mechanics of Adhesion, Dillar, D.A., and Pocius, A.V., Elsevier, Amsterdam cap. 6, 2002.

Tack.

The rapid formation of a bond with the substrate is relevant for the processing of PSAs. The better the tack, the easier the PSA will 'grab' on to the substrate during processing and application, and the lower the risk of unintentional delamination.

Figure 4: Graphic taken from Source 9 Creton, C., and Fabre, P., Chapter 14, Tack in Adhesion Science and Engineering, vol. I: The mechanics of Adhesion, Dillar, D.A., and Pocius A.V., Elsevier, Amsterdam cap. 6, 2002.

Figure 4 illustrates the standard methods to measure tack:

(a) Loop tack method

(b) Rolling ball tack method

(c) Probe tack method

The loop tack method (a) is specified in the ASTM D6195-03, EN 1719 and PSTC-16 standard methods.

A loop of PSA tape is attached to the clamp of a tensile tester. The loop is lowered down to allow contact with a clean substrate. The tensile tester is then reversed so that the PSA tape is detached from the substrate at a controlled rate. The force to detach the PSA tape is measured (see **Figure 6**).

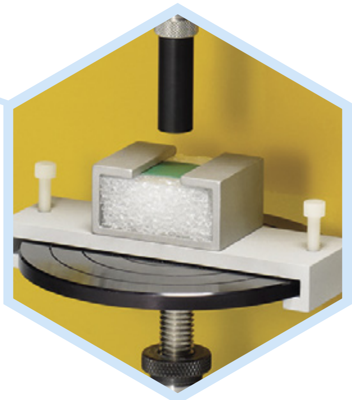


Figure 5: Experimental set up for probe tack test.

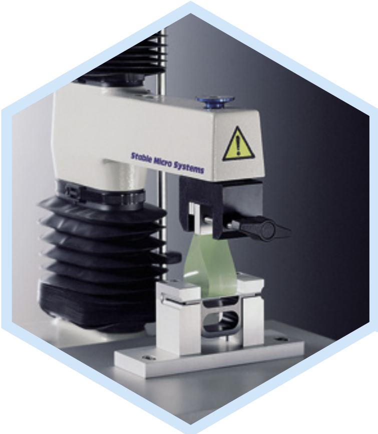


Figure 6: Experimental set up for loop tack test.

This method effectively controls how fast the tape is lowered down to the substrate and how fast the PSA tape is peeled from the substrate, as well as demonstrating the effect of backing stiffness[8].

Another method used to measure tack is the rolling ball method (b). This method eliminates backing effects on the tack measurement and is described in ASTM D3121-06, EN 1721 and PSTC-6 standard methods.

The ramp for the ball has a specified angle and length, and the ball has a specified diameter. The ramp is grooved to ensure the ball rolls straight down the ramp, with the tape to be tested placed at the bottom of the ramp. The tack is assessed by the length the ball travels across the tape: high tack tapes will stop the ball earlier than low tack tapes.

8. Pocius, A. V., Chapter 9, The Chemistry and Physical Properties of Elastomer-Based Adhesives, Carl Hanser Verlag, Munich, Vienna, New York 1997.

Described in ASTM D2979-01, the probe tack method (c) is designed to control all parameters that have an impact on the result. The test measures the short-time, low-pressure adhesion of a flat, cylindrical probe to the adhesive surface. The tack of adhesion is represented by the maximum recorded force required to separate the adhesive surface and the probe[9].

The tape is fixed to a steel plate, which eliminates tape backing effects. The surface of the steel probe is polished to reduce surface roughness and is cleaned before each test. The speed of the probe when lowered onto the adhesive surface (rate of approach) is controlled by the probe tack apparatus, as is the speed of removal from the adhesive surface (rate of detachment).

It must be noted however that the results of probe tack measurements may vary when different measuring equipment is used to test the probe tack[10] (see **Figure 5**).

As with the other measurements, the best way to compare the performance of a PSA is to either generate data for the specific performance parameter using the same experimental set up and method, or run trials on the manufacturing equipment and create 'mock ups' of the final device, and test the performance of the PSA in situ.

Figure 7: Experimental set up for adhesion to steel measurement at an adjustable peel angle.

Peel.

Peel adhesion information from data sheets can help in the broad classification of the adhesives under consideration, such as low, medium and high peel strength. However peel adhesion data is usually adhesion to steel and generated under controlled laboratory conditions, against a smooth, specified steel surface, at a defined peel angle and peel rate as described in method ASTM D3330-33330M, EN 1939 and PSTC101. These conditions are unlikely to replicate those that the PSA will be subjected to as part of a medical device.

Adhesion to steel is a quality control (QC) tool used to document batch to batch consistency of the adhesive manufacturing process. However it is important to remember that these QC data do not reflect real-life performance.

High or low peel force in itself does not provide a measure of the usefulness of a PSA. For example, a very strong PSA would not be suitable for most stick-to-skin applications, while an easy-peel PSA would not be suitable for fixing a display for a blood glucose meter in place.

Many manufacturers employ ASTM standardised methods for their QC, although some use variations of the standard or internal company methods. This makes it almost impossible to gauge an adhesive's performance for a specific application, based on adhesion to steel values in a data sheet.

Tsaur et al[11] published data relating to the impact of the following variables on the peel adhesion of PSAs:

- Peel angle
- Peel rate
- Temperature
- Tape backing

The same PSA can exhibit different peel force measurement results when tested at a 90º or 180º peel angle[12 13]. Unfortunately, there is no easy rule to relate peel angle to peel force: some PSAs show the highest force at the lowest peel angle and vice versa.

One source of these differences is the change in peel rate with a change in peel angle. With a constant sled rate, the peel rate increases with reduced peel angle.

The change in peel rate with a change in peel angle matters because PSAs are viscoelastic liquids. Viscoelastic liquids possess the characteristics of both liquids and solids, and show a more viscous, liquid-like behaviour when under compression. In order to make a PSA bond, it needs to be exposed to sufficient pressure to make it flow. The pressure aids the so-called 'wetting out' process of the adhesive, and hence the bond formation with the substrate.

9. Creton, C., and Fabre, P., Chapter 14, Tack in Adhesion Science and Engineering, vol. I: The mechanics of Adhesion, Dillar, D.A., and Pocius, A.V., Elsevier, Amsterdam cap. 6, 2002.
10. Tirumkudulu, M., and Russel, W.B., On the measurement of "tack" for adhesives, Vol 15, No 6, Physics of Fluids, June 2003.
11. Tsaur, A.T., Tsaur, T., PSTC publications, http://www.pstc.org/i4a/pages/index.cfm?pageID=4417
12. Gardon, J.L., (1963), ASTM Special Technical Publication No. 360, 66th Annual Meeting Papers, Atlantic City, New Jersey.
13. Aubrey, D.W., (1977), Development in Adhesives I, Wake, W. C., (ed.) London: Applied Science Publishers, Ltd., pp 127-156.

A viscoelastic liquid shows more elastic, solid-like behaviour the faster one attempts to deform it. When peeling a PSA away from a substrate surface the adhesive is deformed:

- If the adhesive is peeled slowly, and therefore deformed slowly, it behaves in a more liquid-like manner
- Peeling it away faster means the PSA will show more solid-like characteristics, resulting in an increased peel force with higher peel rate.

This is true up to a peel rate so fast that the PSA hardens to breaking point resulting in a lower peel force than at slower peel rates.

Figure 8 shows an example of how peel force can change when peel rate is changed. The same adhesive can show very different peel force results for different peel rates.

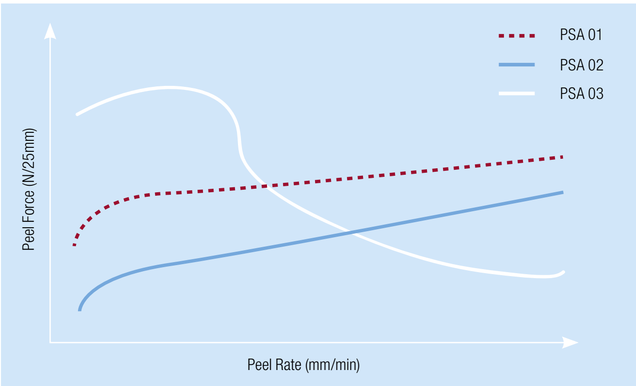


Figure 8: Peel Rate vs Peel Force at constant peel angle, graph adapted from Source 9: Tsaur, A.T, Tsaur T, PSTC publications, http://www.pstc.org/i4a/pages/index.cfm?pageID=4417

Viscoelastic liquids alter their behaviour not just through compression and deformation: they change with increasing temperature from more solid-like to more liquid-like behaviour.

The optimum performance temperature of a PSA is influenced by its formulation. Again, bear in mind that high or low peel force values on a data sheet do not elicit anything about the usefulness of a PSA for a specific application.

Figure 9 shows some example curves of adhesion values for three different adhesives across a temperature range of -10° to +80° C.

This clearly shows the vital importance of testing PSA performance at the relevant temperature range for their particular application. Good performance of a PSA, as tested at a temperature specified in standard methods (e.g. ASTM specifies 23ºC ± 1º, 50 ± 5%RH), gives no indication of its performance at lower or higher temperatures.

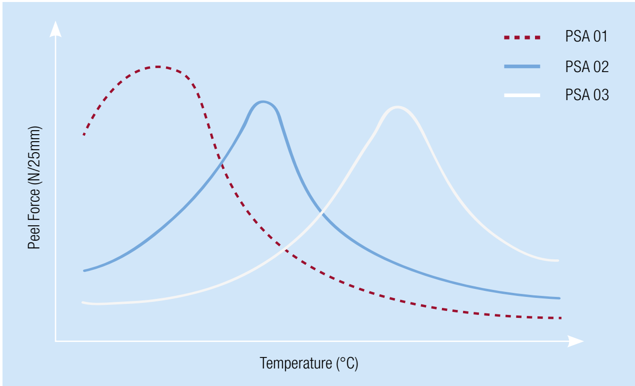


Figure 9: Peel Rate vs Temperature at constant peel angle and peel rate, graph adapted from Source 11: Tsaur, A.T, Tsaur, T., PSTC publications, http://www.pstc.org/i4a/pages/index.cfm?pageID=4417

Shear.

The shear strength of an adhesive is closely linked to its cohesive strength and creep behaviour. Dependent on the application, the main stress on a PSA may be a shear stress, for example the adhesive holding an ostomy bag in place is mainly under shear stress. As with the peel adhesion test, the shear strength test is typically employed in QC to ensure the manufacturing process is under control.

The methods for assessing shear strength use steel or fibreboard as the adherent, a 1kg mass suspended from the PSA tape under investigation, and a timing device. The test measures the time it takes for the PSA to fail, i.e. for the weight to drop[14].

Similar to the peel adhesion test, in order to control the application pressure, a standardised roll weight is used to apply the PSA tape to the test surface. The environmental conditions for this test must be tightly controlled as higher test temperature usually leads to shorter time to failure for the PSA. Furthermore, the pressure used to attach the PSA to the adherent has to be reproducibly controlled.

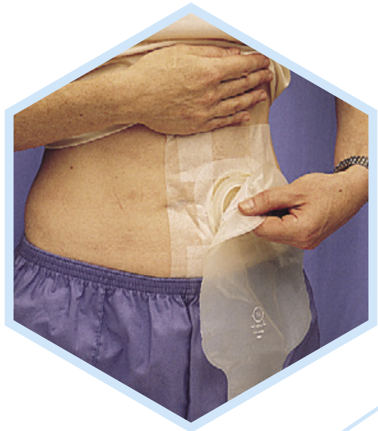
As with peel data, the information from a data sheet can only be employed to broadly categorise the PSAs into low, medium and high shear strength. To make any judgment on how well a certain adhesive will perform in a specific application, it should be tested in the context of that application.

Liner release.

Liner release is one of the properties rarely considered during application development. It may not be relevant for the final application but, particularly for double-coated tapes, the liner release and specifically the differential in liner release can be vitally important to the smooth running of manufacturing processes.

When processing a double coated tape, the liner for the adhesive side which is laminated first in the manufacturing process should release easier than the liner for the adhesive side which is laminated later in the process. If this is not the case the phenomenon of liner confusion may occur.

This means that the liner protecting the adhesive for the later manufacturing step delaminates during tape processing, exposing the adhesive to the environment. The adhesive can pick up dust and other contamination, which dulls the adhesion and may cause lamination failure. Also, the exposed adhesive may contaminate rollers and other parts of the manufacturing equipment.



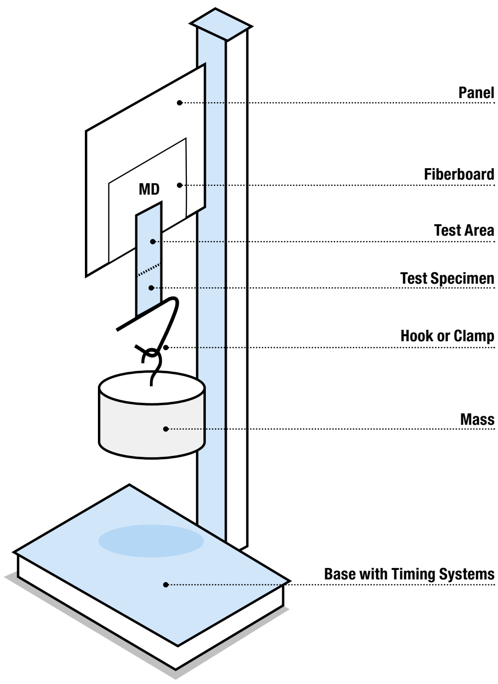


Figure 10: Shear adhesion tester as pictured in ASTMD3654.

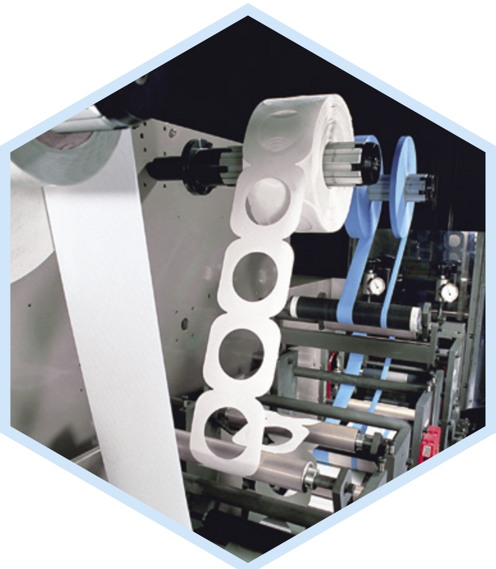
14. ASTM Standard Test method for Shear Adhesion of Pressure-Sensitive Tapes, D3654/D3654M-06, www.astm.org

Methods to measure liner release.

The liner release force, or force differential for double-coated tapes and transfer adhesives, can be assessed from manufacturer data sheets. However, as with the other parameters, whether the liner release is appropriate for the process, or the release force differential is sufficient, can only be tested when the PSA tape or transfer adhesive is used in the process in question, or at least tested under processing conditions.

In generating application related liner release data, the release forces should be measured as per the liner adhesive combination the designer plans to use in the manufacturing process. Some manufacturers publish liner release data on their data sheets which has been generated using method PSTC 4.

Method PSTC 4 is a standard method to enable the performance comparison of release coatings. As such, PSTC 4 uses a standard tape to test the release coating performance. However, for the product designer it is important to ensure that the release force for the liner tape combination intended to be used in the process is performing to expectation.



MVTR.

For stick-to-skin applications, the breathability of a PSA or a soft silicone gel adhesive and backing can be very important. If the application requires the tape to remain on the skin for longer periods of time, it is necessary to enable the skin to 'breathe' to ensure good skin health.

The adhesive and backing breathability in advanced wound care applications have an impact on the total fluid handling of an advanced wound care dressing via excess moisture evaporation, thus prolonging its wear time.

Methods to measure MVTR.

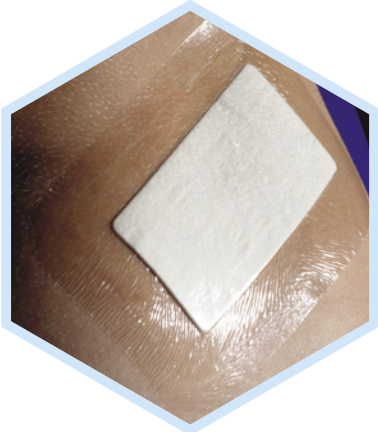
The widely used European standard method to measure MVTR is the Paddington Cup method, BS EN 13726-2:2002[15].

Standard methods are not identical in Europe and the U.S.A, and are also occasionally customised by tape manufacturers. Therefore data published in data sheets should only be compared if generated using the same method.

Furthermore the variability of MVTR values, even when the same method is used to generate these data, is relatively high. The accuracy for BS EN 13726-2:2002 is +/- 15%, which means it is advisable to use a control in the sample set. Ideally, MVTR data for all the materials to be compared should be generated in the same experiment.

16. EN 13726-2:2002, Test method for primary wound dressings – Part2: Moisture vapour transmission rate of permeable film dressings, www.en-standard.eu

Figure 11 shows the results of a Paddington Cup experiment according to BS EN 13726-2:2002, measuring the MVTR of a number of different polyurethane (PU) films coated with an acrylate adhesive. Five samples of each material were tested, averages shown in the graph.



When only the average MVTR is quoted (without the method variability), as is common on a data sheets, it is possible to conclude there is a significant difference in MVTR of these materials. With the error bars included, the individual results of all but one of the coated films overlap. A two tailed t-test, using the material with the highest MVTR (material 5) as the reference, shows there is no statistically significant difference between the MVTR of all but one (material 4) of the tested samples.

If a breathable adhesive tape is to be employed in a multi-layered advanced wound dressing, it is advisable to measure the overall fluid handling capability of the device rather than the MVTR of a single component.

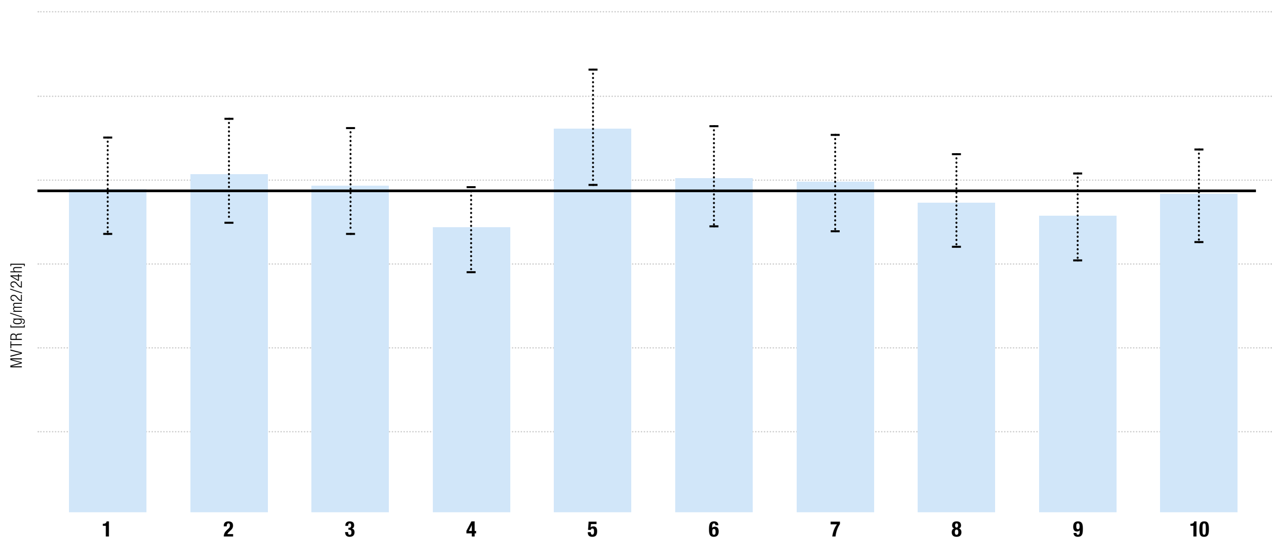


Figure 11: MVTR results for various breathable backings, Paddington cup method, EN13276-2:2002 3M Unpublished Data.

Conclusion

For any PSA manufacturer, it is ideal to have a variety of PSA formulations and strengths available, to be able to accommodate a wide range of applications. Different formulations are optimised for different performance characteristics. For example adhesives with the same peel adhesion can show differences in resistance to shear or initial tack and adhesives exhibiting the same resistance to shear can have different values of initial tack.

Some PSA manufacturers do not always give clear information on the methods employed to generate the data published in data sheets. A manufacturer should supply relevant method information or make the methods available on request, to enable fair comparison of adhesive performance. If the methods are the same, the performance data can be used at the design stages to broadly classify the adhesives.

However, data published on data sheets is generated in accordance with standard or manufacturer-specific methods under controlled conditions, and used as a QC tool for the PSA manufacturer.

Therefore, minimal information can be gleaned from data sheets with regard to PSA performance in a medical device construction.

After the adhesive is chosen, data sheets and certificates of analysis are valuable in assessing the batch-to-batch consistency of the adhesive performance which gives an indication of how well the manufacturing process is controlled.

However, when it comes to process and application specific performance-based selection of a medical tape, there is no substitute for having samples to test the adhesive tape performance in the medical device construction, and on the processing line.

A PSA manufacturer should be able to offer samples and technical support to assist the device designer and process engineer in choosing the right adhesive tape for the application and for smooth processing.

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Fig. 5 Photo courtesy of Brookfield Engineering Laboratories, Inc.
Fig. 6 Photo courtesy of Stable Micro Systems Ltd.
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