

Influence of patch-test application tape on reactions to sodium dodecyl sulfate

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There remains much room for improvement in the accuracy of the patch test procedure. There has been a lack of knowledge regarding the possible relationship between the intensity of test reactions and the quality of the tape used to apply patch tests. Using different brands of tape, patches coated with 2 mg/cm² sodium dodecyl sulfate (SLS) were applied for 24 h to the backs of 10 volunteers. The tape specimens varied in terms of manufacture, elasticity, adhesive strength, and water permeability. The intensity of patch test reactions, evaluated visually and objectively with both the high resolution laser Doppler perfusion imaging technique (HR-LDPI) and transepidermal water loss measurements (TEWL), varied significantly with the different brands of tape. Observed variations in the intensity of reactions to the patch tests could not be explained by any of the 4 tape parameters investigated. In order to attain optimal test quality in the future, both the tape and patches used in the testing system should be standardized and clearly labelled.

Key words: patch testing technique; bioengineering methods; visual assessment; effect of application tape; sodium dodecyl sulfate; laser Doppler perfusion imaging; transepidermal water loss.
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The reproducibility of patch test reactions is far from optimal. A variety of factors may influence the intensity of reactions, including the vehicle used, the manufacturing process of the test material, the application technique, length of exposure to the allergen, characteristics of the test site, and the device used for application (1–4). Individual variables such as sex, age, atopy, extent of dermatitis, number of positive reactions, sleeping habits, and stage of the menstrual cycle may also affect the reproducibility of a test (5). In addition, interpretation guidelines for the test differ and weak reactions are often difficult to interpret (6). Different brands of tape may be used with different testing systems (7, 8). Previously, the effects of application tape on the intensity of patch test reactions has not been considered as a factor that may influence the quality of patch tests. In tests with diesel oils, significant variations in the intensity of test reactions were observed with different brands of tape used to apply large Finn Chambers (9). This stimulated us to investigate the possible relationship between the intensity of test reactions and the brand of tape used to apply patch tests.

Materials and Methods

Sodium dodecyl sulfate (Fluka Chemie AG, Buchs, Switzerland). Polyvinylpyrrolidone (PVP) Polyvidon 90 (Pharmacia AS Hillerød, Denmark). Adhesive strength and elasticity of the tapes was evaluated with a traction machine, Versa Test Advanced Force Gauge, AFG-250N (Mecmesin Ltd., West Sussex, England). Superficial skin blood-flow was evaluated with a high-resolution laser Doppler perfusion imager PIM 1.0 (HR-LDPI), using the analysis program LDI version 3.4. (Lisca Development AB, Linköping Sweden). Water loss was evaluated with the TEWL meter, Evaporimeter EP2 (Servo Med AB, Kinna, Sweden). Tape brands are described in Table 1.

16 volunteers, 6 men and 10 women, aged 19–55 years, were recruited through advertisements. Approval for the experiment was obtained from the Ethical Committee of Karolinska Institute, Stockholm (No. 130/95). SLS patches were produced by printing an SLS/PVP gel on transparent polyester sheets with a dosage of 2.02 mg/cm². Control patches were produced from sheets printed with

Table 1. Type, name and manufacturer of application tapes

Type	Name and manufacturer
cotton fabric backing, zinc oxide rosin/rubber adhesive	Leucoplast, Beiersdorf AG, Hamburg, Germany
artificial silk fabric backing, polyacrylate adhesive	Fixomull Non-stretch, PZN 1598695, Beiersdorf AG, Hamburg, Germany
non-woven cellulose backing, polyacrylate adhesive	Scanpor, Norgeplaster, Kristiansand, Norway
non-woven polyester fibre backing, polyacrylate adhesive	TT-tape, 50-8838-00, Batch 43856, Cederroths, Netherlands
thick perforated polyethylene film, polyacrylate adhesive	Hypafix, #4209, Smith & Nephew, Fisch Laboratories, Vibraye, France
thick non-perforated polyethylene film polyacrylate adhesive	Abufilm Transp., Smith & Nephew Fisch Laboratories, Vibraye, France
thin elastic polyurethane wound film with varying permeability to water vapor, polyacrylate adhesive	Blenderm, 3M Health Care, St. Paul, MN, U.S.A.
	OpSite Flexi-fix, #66000040, Smith & Nephew Medical, Hull, England
	Tegaderm 1626 W, 3M Health Care, Borken, Germany (Made in Canada)
	Tegaderm 9536 HP, Lot 2000-03 BA, 3M Health Care, Borken, Germany (Made in Canada)

PVP gel only. Square patches measuring 12×12 mm were then cut from these sheets (10, 11).

The adhesive strength of application tape was evaluated by means of a traction test from a metal plate. Using a 2-kg roller, strips of tape measuring 8×2.5 cm were rolled onto a polished metal plate cleaned with petroleum ether, and left in place for at least 15 min. The temperature of the room was 21–23°C, and the relative humidity 32–34%. Tape strips were removed at an angle of 180° at a constant speed of 500 mm/min. Traction force was measured at 0.2-s intervals. The full adhesion force was calculated as the mean of the traction forces when constant traction level had been reached. Elasticity was measured in terms of distance from the point at which $\frac{1}{2}$ the full adhesion force had been reached to the point at which the initial starting force was again reached. A mean was calculated from 5 experiments.

Tape traction on human skin

Strips with a width of 2.5 cm were produced from the different brands of tape. Each strip contained an adhesive section of 4 cm length, followed by an SLS patch and a control patch. The strips were applied to both sides of the spine on the backs of the volunteer subjects, horizontally and at random in 2 rows of 5 strips each, using the roller technique described above. After 24 h, TEWL measurements of the adhesive sections were taken through the tape. The tape strips were then removed, with the traction machine at an angle of 180° and a constant speed of 500 mm/min. The adhesive strength of the tape was measured with the technique described above, from the mean of 16 experiments.

2 h after the removal of the tape strips, the SLS and control patches for 10 of the volunteers were

evaluated clinically with LDPI and TEWL measurements. Clinical evaluation symbols: ?, discreet erythema; +, weak erythema; ++, moderate erythema; +++, strong erythema. Evaporimeter measurements were carried out with a 30-cm-high closed compartment covering the back of the volunteer. The investigator used gloves during the

Table 2. Tape adhesion; traction force required to draw the tape from a metal plate and the skin

	Adhesion metal (N) (n=5) mean value 95% CI	Adhesion skin (N) (n=16) mean value 95% CI
Leucoplast	9.7±0.9	1.9±0.4
Fixomull non-stretch	3.1±0.2	1.5±0.3
Scanpor	2.6±0.2	2.1±0.3
TT-tape	4.4±0.3	1.5±0.3
Hypafix	3.1±0.2	1.1±0.3
Blenderm	3.5±0.3	0.8±0.2
Abufilm	2.5±0.3	0.9±0.2
Opsite	3.5±0.2	2.0±0.3
Tegaderm W	3.1±1.1	1.7±0.3
Tegaderm HP	5.3±1.1	1.3±0.3

Table 3. Tape elasticity. Tape length at $\frac{1}{2}$ maximum adhesion

	Extension metal (%) (n=5) mean value 95% CI	Extension skin (%) (n=16) mean value 95% CI
Leucoplast	109.0±3.3	111.3±10.0
Fixomull non-stretch	110.0±5.8	103.5±7.8
Scanpor	107.0±2.1	114.4±4.9
TT-tape	110.5±2.7	108.2±7.6
Hypafix	109.5±5.9	105.4±7.9
Blenderm	103.0±2.1	100.0±12.3
Abufilm	104.0±4.1	106.6±8.5
Opsite	148.0±4.4	116.3±5.6
Tegaderm W	131.5±7.5	121.0±11.3
Tegaderm HP	180.0±22.2	117.2±7.1

measurements. Evaporimeter values were calculated as the sum of water loss from the SLS-areas minus water loss from the corresponding control areas.

HR-LDPI readings were performed at a distance of 15 cm, with a background threshold of 6.1V, an amplification factor of 1.0, and a perfusion scale of 0.00–10.0 V, with the laser head parallel to the skin. The reading area was 30×30 pixels at low resolution, which corresponded to an area of 3×3 cm. The SLS test evaluation areas were located in the center of the reading areas and measured 15×15 pixels. The increase in blood flow was calculated as the mean of readings for SLS test evaluation areas, minus the mean of control areas, for which size, brand of tape, experiment, and evaluation technique were all identical.

The Student *t*-test was used to calculate differences between test reactions.

Results

Forces required to remove the tape strips from the metal plate and from the skin are shown in Table 2. Elasticity values of the tape strips removed from

Table 4. Water vapor permeation through tape after 24 h application

	TEWL (g/m ² /h) (n=16) mean value 95% CI
Leucoplast	2.8±0.9
Fixomull non-stretch	4.8±2.3
Scanpor	6.4±1.8
TT-tape	6.1±1.9
Hypafix	7.4±2.5
Blenderm	2.2±0.5
Albufilm	2.8±0.9
Opsite	7.0±2.1
Tegaderm W	5.7±1.2
Tegaderm HP	8.4±4.0

the metal plate and from the skin are shown in Table 3. Water permeability of the tape strips are shown in Table 4. The means of LDPI and TEWL readings of the SLS patches, minus the corresponding means for control patches of the different tapes, are given in Fig. 1 and Table 5a. Table 5 b presents means and 95% C.I. of the LDPI and TEWL readings of the control patches. Table 6

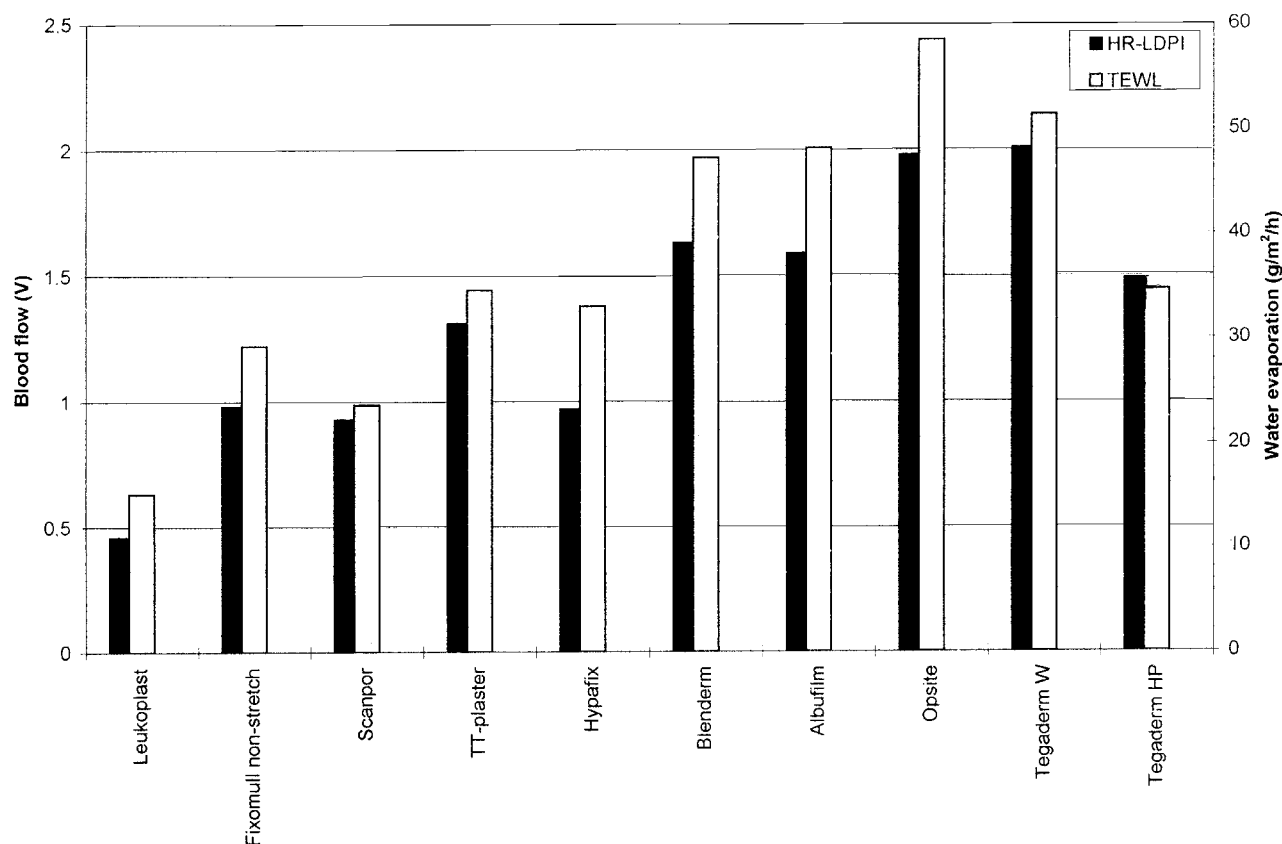


Fig. 1. Intensity of SLS patch test reactions evaluated with HR-LDPI and TEWL.

Table 5 a. Intensity of SLS patch test reactions subtracted with control patch test reactions evaluated with HR-LDPI and TEWL

	HR-LDPI (V) (n=10) mean value 95% CI	TEWL (g/m ² /h) (n=10) mean value 95% CI
Leucoplast	0.5±0.3	15.2±9.2
Fixomull non-stretch	1.0±0.6	29.3±15.2
Scanpor	0.9±0.6	23.7±12.7
TT-tape	1.3±0.8	34.7±18.2
Hypafix	1.0±0.5	33.1±15.9
Blenderm	1.6±0.6	47.3±16.1
Albufilm	1.6±0.6	48.2±18.2
Opsite	2.0±0.8	58.5±22.2
Tegaderm W	2.0±0.8	51.4±20.1
Tegaderm HP	1.5±0.8	34.7±15.0

Table 5 b. Intensity of control patch test reactions evaluated with HR-LDPI and TEWL

	HR-LDPI (V) (n=10) mean value 95% CI	TEWL (g/m ² /h) (n=10) mean value 95% CI
Leucoplast	0.5±0.1	8.8±2.0
Fixomull non-stretch	0.5±0.2	8.4±2.3
Scanpor	0.5±0.2	8.5±2.1
TT-tape	0.5±0.1	9.0±2.7
Hypafix	0.5±0.1	9.0±2.1
Blenderm	0.5±0.1	9.3±1.6
Albufilm	0.5±0.2	10.0±2.6
Opsite	0.5±0.2	10.0±1.9
Tegaderm W	0.5±0.1	10.6±3.3
Tegaderm HP	0.5±0.1	8.6±1.4

Table 6. Results of the Student *t*-test for values in Table 5 chosen for 3 tapes, 1 giving strong, 1 giving moderate and 1 giving weak SLS reactions against SLS reactions for other tapes; only *t*-tests with significant difference (± 2.101) for at least one of either LDPI or TEWL methods have been included in the table

		LDPI (<i>t</i> -value)	TEWL (<i>t</i> -value)
Opsite (strong SLS reactions)	Leucoplast	3.98	3.97
	Fixomull	2.21	2.39
	Scanpor	2.30	3.00
	Hypafix	2.36	2.05
Scanpor (moderate SLS reactions)	Albufilm	-1.65	-2.44
	Blenderm	-1.75	-2.54
	Opsite	-2.30	-3.00
	Tegaderm	-2.36	-2.57
Leucoplast (weak SLS reactions)	TT-tape	-2.31	-2.10
	Hypafix	-1.90	-2.15
	Albufilm	-3.62	-3.56
	Opsite	-3.98	-3.97
	Tegaderm W	-4.03	-3.61
	Tegaderm HP	-2.77	-2.44

presents significant reaction differences for all brands of tape, and 3 brands of tape of different levels of SLS test intensity (strong, moderate,

weak). Clinical evaluation of reaction intensity corresponded well with the LDPI and TEWL measurements. Thin transparent tapes with comparatively greater elasticity had a tendency to be associated with more intense reactions than was the case with either woven or non-woven fibre tapes. The least intense reactions occurred with the old variety of zinc oxide fabric tape. There was no clear correlation between the intensity of test reactions and any of the parameters used to differentiate the various brands of tape.

Discussion

Adhesive tape has many and varied uses in modern society, and there is an extensive literature on the subject of tape adhesion. Much of the knowledge about adhesive tape consists of industrial secrets that are more or less inaccessible. There are conventions regarding measurement and labelling of certain tape parameters. The method is a modified version of the standard method to evaluate tape adhesion (12).

Medical adhesive tapes have undergone rapid development during the last 30 years – from tapes with a backing of pink cotton fabric and an adhesive containing zinc oxide, rosin and/or rubber, which often causes contact allergy, to a diverse assortment of tapes for a variety of purposes. Backings are now manufactured from woven artificial silk, non-woven cellulose or synthetic fibers, and transparent plastic. Polyacrylate is the adhesive most commonly used. Medical adhesive tapes differ with regard to adhesive properties, thickness, elasticity and water permeability. Most tapes can be sorted into one of the 7 categories listed in Table 1. In order to ensure a representative sample for this study, tapes have been selected from all 7 categories. Of the few previous articles that have addressed the issue of tape quality in patch testing, most have dealt with side-effects (1, 13).

Soon after the introduction of the Finn Chamber testing system, there were indications that the 2% concentration of formaldehyde used with AI-testing more often produced skin irritation. Therefore, the concentration was reduced to 1%. Part of the observed increase in skin irritation may have been due to the tape used (1, 14). This example illustrates the influence of testing-system factors on the intensity of patch test reactions.

The study reviewed here found that the type and quality of the tape used to apply test patches to the skin have a significant effect on the intensity of patch-test reactions. Tape quality probably has the same degree of significance for reaction intensity

as do the vehicle and patches used. In the future, this important parameter should be clearly noted. In order to ensure optimal test results, the dose/concentration of the allergen or irritant used should be standardized, along with the tape, patch and vehicle of the testing system. Reported differences in reproducibility between test systems may be due in part to the type of tape used (7, 8).

TEWL and HR-LDPI readings of control tests showed little variation (Table 5b). Control tests were performed with patches printed with PVP, which we consider more relevant than patches without print.

In an attempt to explain differences in reaction intensity associated with the different tapes, 4 different tape parameters were investigated. However, none of them correlated significantly with the intensity of test reactions. We suspect that the micro-elastic properties of the tape, which were not fully investigated, may contribute to observed differences in reaction intensity. It is probable that a tape that holds the patch in constant close contact with the skin will produce more intense test reactions.

It is interesting to note that differences in the adhesive strength of various tapes, as measured by the metal-plate test, correspond only to a limited extent with their adhesive properties on human skin. This is probably due to the precise location of the separation level between tape and object. When tape is removed from the skin, separation takes place at 1 or 2 cell layers beneath the skin surface. A thin layer of cells is detectable on the surface of the tape adhesive after removal; and in most cases, it is not possible to reattach a tape firmly to the skin, because the adhesive layer is partially covered by surface cells stripped from the skin during removal. Tape drawn from a metal plate separates at the juncture of the adhesive and the plate surface. Sometimes a residue of tape adhesive remains on the skin or on the metal plate, in which case separation has occurred within the adhesive layer. This type of separation increases with rising temperature.

Permeation of tape by water vapour varies significantly and is difficult to predict from inspection. Thin elastic wound-dressings and some non-woven tapes with fibre backing have high permeation values. Thick perforated and non-perforated plastic tapes, as well as older types of zinc oxide tape, are usually less permeable. There was no observed correlation between water permeability and the intensity of test reactions.

There was good agreement between visual, TEWL and HR-LDPI assessments. This conforms with our previous experience, which is that TEWL and laser Doppler perfusion evaluations yield ob-

jective, semi-quantitative measurements of irritant patch test reactions (9, 15).

This study has not identified any specific tape that may be considered optimal for patch testing, but has merely disclosed variations in reaction intensity that are associated with different brands of tape. It may be possible to decrease dosages of patch test substances, allergens and irritants, through the use of a thin elastic tape. Tests of weak irritants may be performed without scarification of the skin by using a tape which is associated with strong reactions. Further investigations are necessary to identify a tape that is optimal for attaining reproducible results.

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