

Conformability and irritancy of adhesive tapes on the skin

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The relationship between the conformability of adhesive tape, the mechanical property of the adhesive tape not to interfere with skin movement, and irritation of the skin was investigated. In order to assess the conformability of adhesive tape to the skin, a uniaxial method employing film strips connected to a strain gauge was used to measure the elastic property of the skin, with or without application of various elastic tapes. The tension loaded on the strain gauge was measured while the skin was extended by 15% of its original length in a direction across the humeral axis on the flexor side of the upper right arm. The most elastic adhesive tape showed the best conformity to the skin. The same adhesive tapes were applied on the flexor side of both upper arms so that the tape held a piece of sanitary cotton in place for 24 h. Dermal irritation was not so remarkable in the skin under the inner part of the tapes. On the other hand, the skin reaction was much more severe on the skin under the edge portion of the applied tape which showed poor conformability to the skin. These findings seemed to indicate that the skin reaction was caused by localized distortion of the skin under the edge portion of the applied tapes, during movement of the underlying muscle. Actually, the distortion of the skin surface was great in the areas immediately outside the edge of the applied tape. In conclusion, adhesive tape conformable to skin movement reduced localized distortion of the skin during application, resulting in low irritation at the edge of the applied tape.

Key words: elastic adhesive tape; conformability to skin movement; skin irritation; skin distortion; patch testing technique. © Munksgaard, 1997.

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Irritant contact dermatitis is an adverse effect accompanying the application of pressure-sensitive adhesive tapes. Dermal irritation is caused by occlusion, chemical stimulation by tape materials and adhesive, and stripping of the outer layer of the skin during tape removal. Furthermore, it is well-known that frequently flexing skin tends to be irritated by application of a stiff adhesive tape (1, 2). However, so far as we know, no experimental data are available showing the relationship between the conformability of adhesive tape and its mechanical irritation of the skin. Conformability, the mechanical property of an adhesive tape not to interfere with the skin movement, is considered to be mainly dependent on the elasticity of the tape. We confirm this here by measuring the tension of extended skin, adopting a method of studying the biomechanical properties of human skin, with the application of several adhesive tapes of various elasticity, and report that the skin under the edge of a less conformable adhesive tape tended to be mechanically irritated.

Materials and Methods

Adhesive tapes

3 elastic polyurethane non-woven fabrics, A, B and C, and a non-elastic rayon non-woven fabric, D, were coated with an acrylic adhesive (Nichiban, Japan) to a thickness of 40 μm . Table 1 shows the elastic property, adhesive properties and water vapor permeability of these tapes.

Conformability of tapes to extending skin

10 healthy male volunteers with a mean age of 29.7 years (23–36 years) participated in this study after signing a written consent form. A 10-mm end section of 2, 15-mm-wide strips of non-elastic film was adhered by means of a 15×10 mm double-sided adhesive tape to the skin surface of the flexor side of the upper right arm at an interval of 20 mm, so that the cut ends faced each other in parallel (Fig. 1). The other end of one strips was fixed to an unmoving stand. The free end of another

Table 1. The properties of various elastic adhesive tapes

Tapes	Thickness ^{a)}	Peel adhesion (N/15 mm)		Holding power (mm) ^{c)}	15% modulus (N/15 mm)		Water vapor permeability (g/24 h, m ²)
		bakelite	skin ^{b)}		MD	TD	
tape A	227±18	1.80±0.04	0.64±0.17	0.4±0.1	1.27±0.03	0.78±0.09	3364±341
tape B	375±18	1.99±0.29	0.81±0.24	0.4±0.1	2.27±0.07	1.44±0.02	3564±249
tape C	484±29	1.98±0.84	0.91±0.29	0.5±0.1	3.26±0.13	2.56±0.05	3910±465
tape D	135±3	2.21±0.08	0.66±0.22	0.3±0.1	21.13±1.17	15.00±0.56	3850±41

Each value represents the mean±SD of 3 samples.

^{a)} n=5; ^{b)} n=6; ^{c)} mm/12·20 mm, 200 g, 60 min.

strips was connected to a strain gauge (DFG-2, 2K-R, Shimpo, Japan) which was capable of being moved at a constant velocity (50 mm/min) on the same plane relative to the skin surface, so that the skin between the cut ends of the 2 film strips was extended in a direction across the humeral axis. The tension loaded on the strain gauge was recorded continuously on a recorder (FGT-PR, Shimpo, Japan) while the skin was extended by 15% of its original length. The measurement was carried out with or without application of 1 of 4 test adhesive tapes (15×18 mm) on the skin surface between the cut ends of the 2 film strips. For each person and for each tape (including a control without tape application), the measurement was repeated 3× and the means of the data were utilized. A Latin square design was employed for determining the sequence of the test tapes and the control experiment.

Skin irritation

20 healthy male volunteers with a mean age of 35.8 years (23–55 years) participated in this study after signing a written consent form. The same adhesive

tapes used in testing the conformability to the skin were tested. A tape with a size of 15×80 mm was applied on the skin of the flexor side of both upper arms, so that the tape held a piece of sanitary cotton (30×30 mm, 400 mg) in place. The sequence of adhesive tapes applied was determined using a Latin square design. The tapes on the skin were left untouched for 24 h of the volunteers' usual life-style. Skin reaction was evaluated with visual scoring at 1 h, 4 h, 24 h and 48 h after removal of the tapes. The reaction was scored according to the following scale: 0 – no reaction; 1/2 – very slight erythema; 1 – erythema; 2 – well-defined erythema with slight edema; 3 – severe erythema with edema and vesicles. Scoring was done separately for the edge section and for the inner area of the applied tapes.

Distortion of the skin

6 healthy male volunteers with a mean age of 31.7 years (30–36 years) participated in this study after signing a written consent form. The skin of the

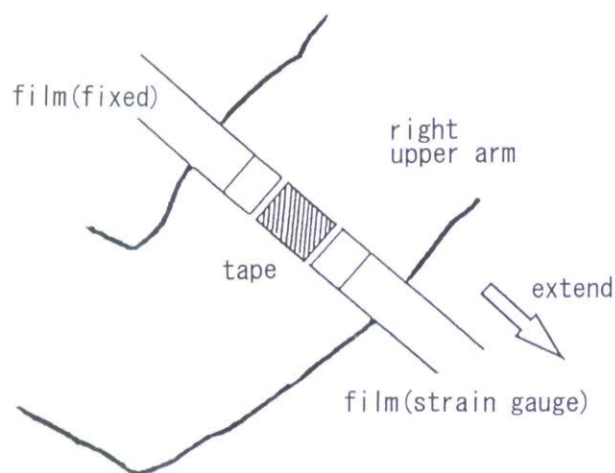


Fig. 1. Schematic drawing of a method for measuring the elastic property of the skin, in order to assess the conformability of adhesive tapes to it.

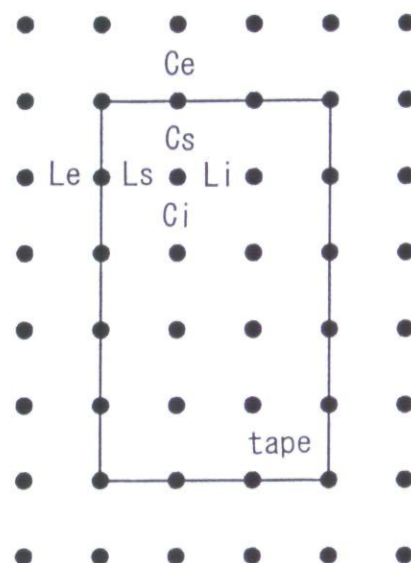


Fig. 2. Schematic drawing of a matrix for evaluating the distortion of the skin on the upper right arm.

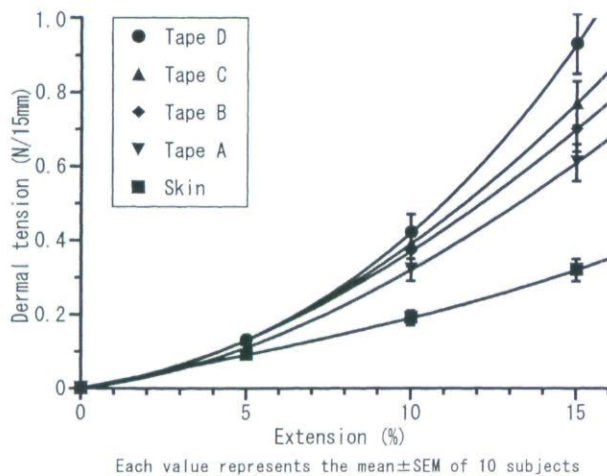


Fig. 3. Dermal tension as a function of extension with or without application of various elastic adhesive tapes on the upper right arm.

flexor side of the upper right arm was dotted with black ink while the cubital joint was extended to form a 6 columns $\times$ 8 rows matrix of 5-mm intervals between dots (Fig. 2). A transparent dressing tape (size, 15 $\times$ 25 mm) backed with a non-elastic carrier film (Cathereep-N, Nichiban, Japan) was applied so that the corners were located just on the dots of the 2nd inner row and column in every direction. The distance, measured by means of an image-processing apparatus (IMAGE ANALYZER V10, Toyobo, Japan) when the cubital joint was flexed, between a dot in column 2, row 3, dot (2, 3) and a dot in column 3, row 3, dot (3, 3), was taken as a standard (Ls) for distortion of the skin in a direction along the humeral axis. Similarly, the distance between dot (3, 2) and dot (3,3) was taken as a standard (Cs) for distortion of the skin in a direction across the humeral axis. The ratio of the distance between dot (1, 3) and dot (2, 3), Le, to Ls, indicated the extent of distortion in a direction along the humeral axis in the skin area just outside of the applied tape, compared to the

area under the edge section of the applied tape. Similarly, the ratio of the distance between dot (3, 3) and dot (4, 3), Li, to Ls, indicated the extent of distortion in a direction along the humeral axis in the skin area under the inner part of the applied tape. The same examination was carried out for distortion of the skin in a direction across the humeral axis. Examination was done before and after the non-elastic carrier film was peeled off and without application of tape as control. The 15% moduli of the tape with the carrier film are 69.3 ± 0.6 N/15 mm (mean $\pm$ SD, $n=3$) in the longitudinal direction and 60.9 ± 8 N/15 m in the transverse direction. Those without the carrier film are 0.93 ± 0.03 N/15 mm and 0.84 ± 0.03 N/15 mm, respectively.

Statistical analysis

Visual scores in the irritation test were analyzed by a non-parametric Kruskal-Wallis test and a Dunnet multiple comparison test.

Results

Fig. 3 shows the tension of the skin as a function of extension with or without application of adhesive tapes. It was found that, as was expected, the most elastic adhesive tape showed the best conformity to the skin. Thus, the increase in tension during extension in the presence of the tape was most similar to that of the skin in the absence of tape application. Though the effect of the adhesive tape on the dermal tension during extension was almost proportional to the elastic property in tapes with relatively highly elasticity (tapes A, B and C), the tape (tape D) with the least elasticity did not exert the large effect expected from its very poor elasticity.

Table 2 shows the irritation by these tapes employed in the test of their conformability on the same skin. Dermal irritation was not so remark-

Table 2. Dermal irritation of the inner part and the edge section under the tapes holding a cotton pad on the upper arm

	Tapes	Time after removal (h)			
		1	4	24	48
the inner part	Tape A	0.38 ± 0.07	0.13 ± 0.06	0.18 ± 0.07	0.10 ± 0.05
	Tape B	0.33 ± 0.08	0.20 ± 0.07	0.18 ± 0.07	0.10 ± 0.05
	Tape C	0.38 ± 0.07	0.23 ± 0.07	0.15 ± 0.05	0.08 ± 0.04
	Tape D	0.47 ± 0.09	0.32 ± 0.08	0.21 ± 0.07	0.11 ± 0.06
the edge section	Tape A	0.30 ± 0.12^a	0.18 ± 0.06^a	0.28 ± 0.12	0.28 ± 0.11
	Tape B	0.55 ± 0.16	0.40 ± 0.15^b	0.33 ± 0.11	0.33 ± 0.12
	Tape C	0.88 ± 0.19	0.55 ± 0.12	0.30 ± 0.09	0.28 ± 0.09
	Tape D	1.00 ± 0.18	0.92 ± 0.17	0.66 ± 0.18	0.66 ± 0.18

Each value represents the mean $\pm$ SEM of 20 subjects.

Statistical analysis: ^{a)} $P < 0.01$ (versus tape D); ^{b)} $P < 0.05$ (versus tape D).

able in the skin under the inner part of the tapes. On the other hand, the skin reaction was much more severe on the skin under the edge of the applied tape which showed poor conformability to the skin in the preceding test. It should be noted that the adhesive tape with the best conformability to the skin (tape A) did not produce a greater reaction in the skin under the edge section, compared with that under the inner part. These findings seemed to indicate that the skin reaction was caused by localized distortion of the skin under the edge of the applied tapes accompanying arm movement. Therefore, the distortion of the skin was examined.

As shown in Fig. 4 and Table 3, the configuration of the skin surface of the flexor side of the upper arm was changed by flexing the cubital joint. The skin constricted in a direction along the hu-

meral axis and extended in a direction across the humeral axis, by flexing the cubital joint in the absence of adhesive tape application. The change in distance between neighboring dots was the same over the whole area, in the absence of any adhesive tape applied. Thus, the ratio of the distance between 2 neighbouring dots to the next one was close to 1.0, because the skin was originally dotted at the same interval. It was clearly shown that this change in configuration of the skin surface under the applied adhesive tape was interfered with, because the distance between neighbouring dots under the tape did not markedly change after flexing the cubital joint. On the other hand, the change in both directions in distance between dots just outside of the applied tape was less or more, compared with that in the absence of the application of tape. The distortion ratio of the skin area just

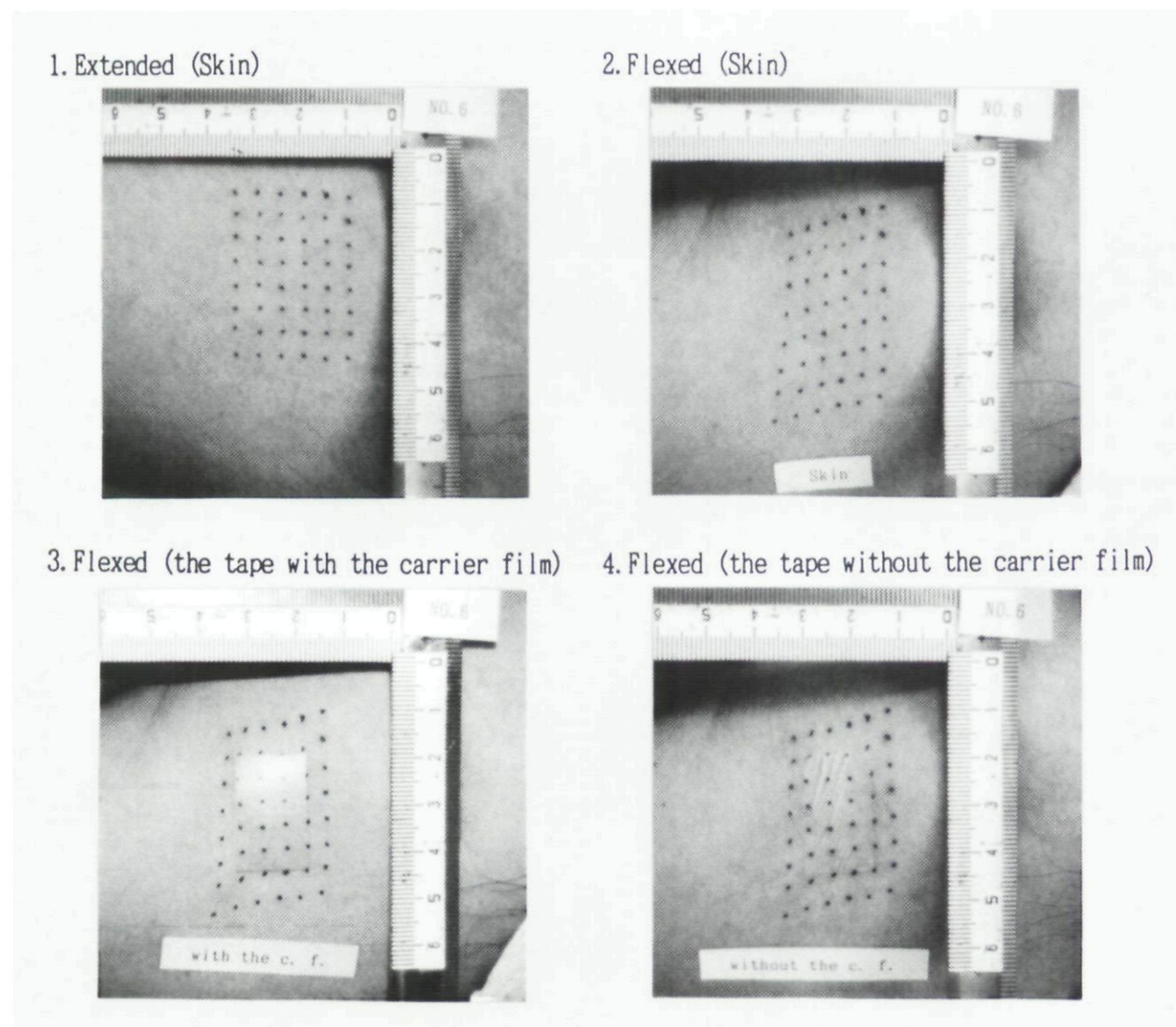


Fig. 4. Distortion of the matrix on the skin with and without application of the tape when the cubital joint was flexed.

Table 3. The distortion of skin with or without application of the tape on the upper right arm

			Extending skin	Flexilng the cubital joint		
				skin	without the carrier film	with the carrier film
along the humeral axis	distance between dots	Le	4.95±0.03	4.35±0.15	3.88±0.17	3.77±0.20
		Ls	5.06±0.07	4.42±0.12	4.59±0.07	4.80±0.07
		Li	5.16±0.08	4.61±0.16	4.91±0.08	5.06±0.08
	distortion ratio	Le/Ls (edge section)		1.00	0.86	0.78
		Li/Ls (inner part)		1.02	1.05	1.04
across the humeral axis	distance between dots	Ce	4.67±0.09	5.21±0.13	5.61±0.18	5.56±0.13
		Cs	5.00±0.11	5.78±0.09	5.10±0.10	5.07±0.10
		Ci	5.09±0.07	5.79±0.04	5.03±0.06	5.03±0.09
	distortion ratio	Ce/Cs (edge section)		0.96	1.18	1.19
		Ci/Cs (inner part)		0.98	0.97	0.97

Each distance value represents the mean±SEM of 6 subjects.

outside the applied tape was other than 1.0. This indicates that localized distortion was produced in the skin surface just under the edge of the applied adhesive tape during movement of the underlying muscle. The effect of the tape as described above was more remarkable before a non-elastic carrier film was peeled off.

Discussion

In this study, we employed a method for measuring the elastic property of the skin in order to assess the conformability of adhesive tapes to the skin. Because mechanical irritation of the skin by adhesive tapes takes place, clearly on the skin in vivo, evaluation by the test described here of adhesive tapes should be made in addition to conventional tests of their physicochemical properties. Our method employing film strips connected to a strain gauge is advantageous over earlier uniaxial methods (3–8), because no gravitational force was applied to the skin. In this study, it was found that the elastic property of the skin in the presence of applied adhesive tapes was largely varied by the modules of elasticity of the tape materials. However, it should be noted that the same adhesive was used on all the tapes tested in this study. The conformability of the tapes to the skin must also be influenced by other adhesive properties; therefore, the present method would be useful for screening an adhesive tape which interfere as little as possible with skin movement.

In preliminary patch testing, it was found that any noticeable irritated skin reaction was not detectable after 48 h application of the test tapes (not published). Therefore, a cotton pad was embedded under the adhesive tape in an attempt to simulate a usual clinical application of pressure-sensitive adhesive tapes. The irritant reaction was more readily produced when a cotton pad was attached.

A striking finding of this study is that skin irritation takes place under the edge portion of the adhesive tape, when tape is poorly elastic. The relationship between conformability of these tapes and irritation of the skin is illustrated in Fig. 5. The irritation of the edge area just outside the applied tape is almost linearly related to the tension of the skin, extended by 15% of the original length in the presence of adhesive tape. The edge reaction should be important in adhesive tape dermatitis, because of its severity and lasting nature, occasionally causing a change in pigmentation. Furthermore, the distortion of the skin surface during movements of underlying muscle was great in the areas immediately outside the edge section of the applied tape. Taken together, it is conceivable that the skin-irritating mechanical stimulation of adhesive tapes is a localized drag on the skin. Therefore, the mechanical irritability of adhesive tape should vary with the conformability to the skin.

Further study employing many various kinds of tapes would be required for full elucidation of the

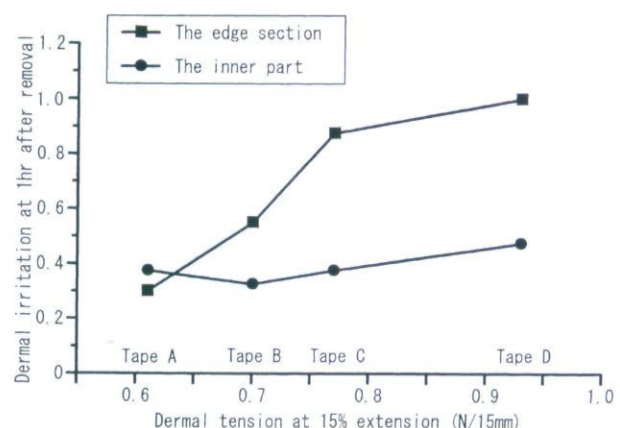


Fig. 5. The relationship between conformability to skin movement and irritation by various elastic adhesive tapes.

precise mechanism of mechanical skin irritation by pressure-sensitive adhesive tapes.

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