THE MECHANISM OF ADHESIVE PLASTER IRRITATION[1]

SAMUEL M. PECK, M.D., HERBERT ROSENFELD, M.D., K. K. LI, M.D., AND ARTHUR GLICK, M.D.

With the assistance of ROSE BERGAMINI, B.A.

The mechanism of cutaneous irritation from adhesive plaster has been studied by relatively few workers despite the great practical importance of the problem. Most of the early investigators concluded that the irritation was largely dependent on individual ingredients in the adhesive substances. Bloch (1), many years ago, stated that one per cent of the population would show reactions to adhesive tape depending on the duration of contact. A recent paper by Sheldon, Hansel and Blumenthal (2) stated that as many as fifty per cent of the subjects in their experiments gave positive reactions to adhesive tape, depending on the formula used.

It is agreed by all who use adhesive tape extensively, and especially by those who employ patch testing as a routine measure, that irritation is to be expected in very many persons on whom adhesive tape is used frequently. A number of observers were able to show that in some instances a specific allergy to some of the ingredients in the adhesive material was responsible for the irritation (2, 3, 4). Grolnick (4) especially has insisted that almost all of the irritation attributable to adhesive tape is caused by mechanical irritation and maceration, allergy playing a role only in occasional instances. However, in the majority of cases of adhesive-tape irritation, a mechanism such as allergy cannot be demonstrated.

Adhesive tape irritation can be divided into three distinct types:

Type 1, which is evanescent and relatively unimportant, consists of erythema and even follicular macules or papules The more adherent the adhesive material and the hairier the area to which it is applied, the more evident is this reaction. In this type the duration of contact is relatively unimportant. The irritation can be termed "reaction of removal" and is a combination of mechanical trauma and probably a certain amount of dermographism.

Type 2 is a severe reaction. It consists of erythema, edema, papules, vesicles and even pustules. The vesicular element is the most prominent. Once this type of reaction has developed, following a definite incubation period of five days or longer, reapplication of the same variety of adhesive tape produces a reaction in twenty-four hours. The irritation may extend beyond the area of application and usually increases in intensity after the tape has been removed. This is the type of reaction which is due to specific allergy to one of the ingredients in the adhesive substance. We agree with Grolnick (4) that this reaction is rare.

Type 3 is a reaction consisting of erythema, papules and pruritus. Vesicles

[1] From the Dermatologic Service and Laboratories of the Mount Sinai Hospital, New York City.

Received for publication January 15, 1948.

are rare. The longer the adhesive tape is in contact with the skin, the more evident the reaction. Edema, erythema and pruritus are characteristic of this reaction. A given variety of adhesive tape may produce different reactions after simultaneous application to different areas of the skin. Even when a severe reaction develops, a subsequent application of the same material may provoke little or no reaction in twenty-four hours. Sensitization to the ingredients of the adhesive mixture cannot be shown to be the cause of this type of reaction. This is by far the most frequent adhesive plaster reaction encountered. Grolnick (4) and others have suggested that this type of reaction may be due to maceration and direct irritation, and that it is not attributable to specific sensitization.

Our interest in this problem was aroused by the original experiments of R. E. Humphries as reported in this JOURNAL (5). Humphries used an adhesive plaster containing the zinc salts of propionic and caprylic acid as bacteriostatic and fungistatic chemicals. With this type of adhesive tape, he encountered only five cases of mild irritation among 130 patients who had developed dermatitis from ordinary adhesive plaster. Many of these patients had had dermatitis severe enough to preclude further use of the adhesive. Humphries (5) advanced the hypothesis that while allergy undoubtedly played a role in some cases of adhesive tape irritation, the bacteria and possibly the monilia on the surface of the skin were chiefly responsible for many of the cases.

CLINICAL EXPERIMENTS

Through the kindness of Dr. Humphries, there was made available to us an adhesive plaster which contained the zinc salts of propionic and caprylic acid.[2] A two-inch square of this plaster was applied to the arms, forearms or backs of 137 adults. Hairy areas were avoided as much as possible. Both male and female subjects were tested. In the majority of instances the adhesive patches were left in place from 7 to 14 days. There were no instances of dermatitis in this test series. This was surprising since it had been our experience that some degree of dermatitis should have occurred in a fair percentage of the cases. It was apparent that the tape was quite adherent. Therefore when the patches were removed, redness and some follicular reaction occurred in a number of instances. This usually subsided very quickly and was interpreted as a purely mechanical reaction of irritation caused by forcible removal of the tape. We did not consider such reactions as true adhesive tape dermatitis.

In 54 cases, tests were conducted with: a) what will be referred to as hospital adhesive tape, (a well-known commercial variety), and b) the special adhesive containing the fatty acid salts. These were applied in the form of two-inch squares to analogous portions of the body for 48 hours, 7 days and 14 days. The special adhesive tended to stick better, without any tendency to curl at the edges or form wrinkles. When the tape was removed, there was a definite slimy layer on the surface of the hospital adhesive; this could not be seen on the special adhesive. While it was not unusual for the patients to complain of itching

[2] The adhesive plaster was obtained through the courtesy of the Seamless Rubber Company.

under the hospital adhesive, no itching was produced by the special adhesive. In a number of instances, seven and fourteen day observations were difficult to complete because the hospital adhesive tape had fallen off.

The reaction of removal (Type 1) was evident with both types of adhesive tape but this disappeared rapidly.

In sharp contrast to this there were *no instances of irritation from the special adhesive tape, and seven cases of irritation from the hospital adhesive tape.* The reactions of irritation were of two types. In 5 cases the skin under the hospital adhesive was red and edematous and sometimes had a glazed appearance. The patients who showed this reaction complained of pruritus in the affected areas. In the other two patients who developed dermatitis from the hospital adhesive, in addition to the redness and edema, there were definite vesicles; in one instance these were quite large. These two patients also complained of pruritus, which was more marked than in the 5 cases previously cited. In 5 of the cases, the reaction was evident in 48 hours and the plaster had to be removed. It was among these 5 cases that we observed the two vesicular reactions already mentioned. In one case, there was an area of redness and swelling but no vesicles on the 7th day; a similar reaction was evident in one case on the 14th day.

While we had at our disposal many of the ingredients which are commonly used in the manufacture of adhesive tape, and while we had all the ingredients of the special adhesive, we did not have all the substances which were contained in the hospital adhesive. Patch tests with the available ingredients of the hospital adhesive tape were carried out in the 7 cases and yielded negative results. We could not exclude the possibility that some of the reactions to the hospital adhesive tape might be caused by specific sensitization to some ingredient for which we had not tested. However, only in the two persons who exhibited vesicular types of irritation did repeated applications of the hospital adhesive regularly produce similar degrees of reaction in 24 hours. It was therefore considered that the majority of these reactions belong to the large group of adhesive tape reactions which were commonly attributed to some type of mechanism other than allergy to ingredients of the adhesive tape formula.

In order to study more closely the reason why the hospital adhesive caused so much more reaction than the special adhesive, it was determined to investigate the pH changes of the cutaneous surface and the bacterial flora of the skin under both adhesives.

pH STUDIES OF THE NORMAL SKIN AND OF THE SKIN UNDER BOTH THE SPECIAL ADHESIVE PLASTER AND THE HOSPITAL ADHESIVE PLASTER

The pH of the surface of the skin was first studied by the use of a colorimetric method described by Bernstein and Herrmann (6). In this method a special indicator is used. According to Bernstein and Herrmann, and also Herrmann, Behrendt and Karp (7), the results compare favorably with those obtained by electrical methods, although the authors admit that the electrometer is probably more accurate. The procedure of Bernstein and Herrmann was carried out on 50 adults, both males and females. Readings were made on the arms, and the

flexor and extensor surfaces of the forearms. It became necessary to discard this method because different observers obtained widely divergent readings on the same patient at the same time. Readings obtained by one of the observers using the flexor surfaces of the forearms, gave a pH of from 2.3 to 6.2 with an average of 3.9.

Blank (8), using a glass electrode and a vacuum tube potentiometer, obtained an average pH reading of 4.45 on the flexor surface of the forearms of the male and an average pH of 5.5 in analogous areas in females. Draize (9), also using a pH meter and glass electrodes, obtained an average pH reading of 4.04 on the arm; the highest pH obtained was 6.66 on the back of the hand of a white female. The average pH for all areas on the skin on a white male was 4.85.

Method

In the following experiments we adopted the technique of Blank and Draize, who used a pH meter and glass electrodes (National Technical Laboratories, Pasadena, California). With this method, the readings on the flexor surface of the forearm varied from pH 4.04 to pH 6.7, with an average of 5.2; on the

TABLE I

pH normal skin average of 14 cases: 5.2

	pH CHANGES UNDER ADHESIVE AVERAGE OF 14 CASES		
	48 hrs.	7 days	14 days
Hospital adh.....	5.6	6.3	6.7
Special adh.....	5.8	5.7	6.4

extensor surface of the arm, the pH readings varied from 4.35 to 6.5, with an average of 5.55; on the back, near the scapulae, the readings varied from 4.5 to 6.5 with an average of 5.2. It can thus be seen that the colorimetric method gave an average pH which was approximately 1.5 lower than the average level obtained by means of a pH meter. Our findings were in agreement with those reported by Blank and Draize.

Three patches of hospital adhesive tape and three of special adhesive tape, each two inches square, were applied to the flexor surfaces of the forearm in parallel rows in 14 patients. The pH was determined at the end of 48 hours, 7 and 14 days.

Results

It can be seen from Table I that the average pH reading on the normal skin of the forearm of these 14 cases was 5.2. At the end of 7 days, the pH under the hospital adhesive averaged 6.3 while under the special adhesive, it was 5.7. By the end of 14 days, the pH under the hospital adhesive showed an average of 6.7 while under the special adhesive, it had risen to 6.4.

It can be seen that the pH increased under both adhesives the longer they were allowed to remain on the skin. There was a greater rise under the hospital

adhesive than under the special adhesive. This was most evident in the 7 day readings. The difference in the pH under the two types of adhesive tape did not seem great enough to account for the marked difference in the degree of irritation produced. Perhaps when the change in pH, especially on the 7th day, is correlated with the bacteriologic studies described below, the difference in pH values may assume greater significance.

THE BACTERIAL FLORA OF THE NORMAL SKIN AND OF THE SKIN UNDER ADHESIVE TAPE

An attempt was made to study the bacterial flora on the normal skin of the flexor surface of the forearm in 14 additional cases; both male and female patients were tested. As in the previous experiment, two parallel rows of two-inch squares of adhesive tape were placed on the forearm. Each of the two varieties of adhesive tape were thus used, in triplicate. Cultures were taken from the normal skin and from the skin under each of the tapes at the end of 48 hours, 7 days and 14 days.

Method

The method used for the study of the bacterial flora was that described by Pillsbury and Nichols (10). Two cotton swabs were sterilized in a test tube at 180° Centigrade for two hours. Just before use, 0.5 cc. of sterile broth was added to the tube under sterile precautions. The two sterile cotton swabs, held together and used as one, were brushed with moderate pressure over the skin. Equal areas of skin were brushed. In culturing the skin under the adhesive plaster care was taken not to brush the skin beyond the area of contact with the adhesive tape. The swabs were replaced in the original tube and immediately taken to the laboratory and placed in infusion broth. They were incubated overnight aerobically and for 48 hours anaerobically. Sub-cultures of the broth were made on blood agar.

Results

The results of the experiments are summarized in Table II.

Normal Skin. Six organisms were isolated 31 times in the aerobic cultures. A Corynebacterium was isolated 11 times, a Sarcina 7 times; a Micrococcus 4 times; Staphylococcus albus 4 times; a Gram positive spore-bearing bacillus 3 times, and Staphylococcus citreus once. Four organisms were isolated in the anaerobic cultures. A Corynebacterium was found 6 times, a Gram positive spore-bearing bacillus 5 times, Staphylococcus albus 3 times, Sarcina twice. Pillsbury and Nichols (10) found that the Micrococcus was the most frequently encountered organism aerobically and anaerobically with this method.

Hosptial Adhesive Tape. Seven species of bacteria were isolated under all of the strips of hospital adhesive tape in the 14 persons in 42 attempts aerobically; 6 species were encountered 21 times anaerobically. The Micrococcus was encountered 6 times aerobically and once anaerobically; Staphylococcus albus 7 times aerobically and 6 times anaerobically; the Sarcina 3 times anaerobically;

the Streptococcus indefinite twice anaerobically; the Gram positive spore-bearing bacillus once aerobically and Streptococcus non-hemolyticus and B. subtilis each once aerobically. The Micrococcus and Staphylococcus albus were the most frequent organisms found while the Corynebacterium and Sarcina were

TABLE II

	FREQUENCY ON NORMAL SKIN, 14 NORMAL CASES	FREQUENCY UNDER HOSPITAL ADHESIVE			FREQUENCY UNDER SPECIAL ADHESIVE			TOTAL UNDER HOSP. ADH.	TOTAL UNDER SPECIAL ADH.
		48 hrs.	7 days	14 days	48 hrs.	7 days	14 days		
Corynebacterium									
Aer.	11	0	1	0	0	0	0	1	0
Anaer.	6	0	1	1	0	0	0	2	0
Sarcina									
Aer.	8	0	0	0	0	2	3	0	5
Anaer.	2	0	2	1	1	0	0	3	1
Micrococcus									
Aer.	4	2	2	2	3	1	1	6	5
Anaer.	0	2	3	1	3	0	1	6	4
Staph. albus									
Aer.	4	1	3	3	1	1	0	7	2
Anaer.	3	2	2	2	2	1	2	6	5
Gram. posit. Spore bearing									
Aer.	3	0	0	1	0	0	0	1	0
Anaer.	5	0	0	0	0	0	0	0	0
Staph. citrus									
Aer.	1	0	0	0	0	0	0	0	0
Anaer.	0	0	0	0	0	0	0	0	0
Staph. aureus									
Aer.	0	0	0	0	1	0	0	0	1
Anaer.	0	0	0	0	0	0	0	0	0
Streptococcus non hemolytic.									
Aer.	0	0	0	0	0	0	0	0	0
Anaer.	0	1	0	0	0	0	0	1	0
Strept. indef.									
Aer.	0	0	0	0	0	0	0	0	0
Anaer.	0	1	1	0	0	0	0	2	0
B. subtilis									
Aer.	0	0	0	0	0	0	0	0	0
Anaer.	0	0	0	1	0	0	0	1	0
Summation									
Aer.	31	3	6	6	5	4	4	15	13
Anaer.	16	5	9	7	6	1	4	21	10

much less frequently encountered than on the normal skin. Considering that there were 42 cultures taken as against the 14 for the normal skin, it would appear that the bacterial flora under the hospital adhesive was decreased as compared to that on a normal skin. The diminution in the bacterial flora was most evident after 48 hours with a gradual increase to a maximum on or about the 7th day. This was much more evident in the anaerobic cultures.

Special Adhesive Tape. 5 organisms were isolated in 42 attempts. 4 of the organisms were isolated 13 times aerobically and 4 ten times anaerobically. The Micrococcus was isolated 5 times aerobically and 4 times anaerobically; the Sarcina, 5 times aerobically and once anaerobically; Staphylococcus albus, twice aerobically and 5 times anaerobically and Staphylococcus aureus once aerobically. The Corynebacterium was not found under the special adhesive.

Not only was there a distinct decrease in the bacterial flora as compared to the normal skin but also as compared to the hospital adhesive. This was especially noticeable on the 7th day. Here it can be seen (see Table II) that 16 positive cultures were obtained anaerobically in 14 attempts from the normal skin; 9 positive cultures anaerobically out of the 42 attempts on the 7th day under the hospital adhesive and only one anaerobically out of 42 attempts on the 7th day under the special adhesive.

It is obvious that by this method we were not evaluating the bacteriostatic action of the ingredients of the adhesive plaster but the bactericidal action. Any bacteriostatic effects would be nullified once transfer was made into the broth. In order therefore to determine the presence of bacteriostatic action, optical density studies of the first broth cultures were attempted at the end of 12 hours. It was found that the swab technic employed introduced tiny particles of cotton which interfered with the optical density readings so that fine differences could not be estimated.

Apparently the bacterial flora of the normal skin ordinarily changes under adhesive tape. The Corynebacterium and the Sarcina which were most frequently encountered on the normal skin had practically disappeared under both types of adhesive tape and the Micrococcus and the Staphylococcus albus which were rather infrequently encountered in the routine cultures of the normal skin had apparently increased under both kinds of tape. However, it can be seen from Table II that, although these organisms were found under the special adhesive tape in many instances at the end of 48 hours, they too had practically disappeared at the end of 7 days. *There is a striking decrease in bacterial flora under the special adhesive as compared with the hospital adhesive.* This was especially noticeable on the 7th day in anaerobic cultures.

If we were to assume that the bacterial flora and the pH played a role in nonallergic irritation produced by adhesive tape, we would have an explanation of why this type of irritation was found to occur under the hospital tape and not under the special tape. Since known bacteriostatic substances were included in the special adhesive tape, it was not surprising that there was such a difference between the culture findings under the two adhesives. We did not expect, however, to find such a decided bactericidal effect as was apparently demonstrated. One is tempted to evaluate the role of one or the other of the organisms as a possible etiologic agent in adhesive tape irritation. It was striking that the Micrococcus and the Staphylococcus albus were found much more frequently under the adhesive which showed the greater degree of irritation. However, conclusions as to the role of any one organism in adhesive tape irritation cannot be made under the experimental conditions outlined.

BACTERIAL FLORA OF SKIN IRRITATED BY ADHESIVE TAPE

In order to study the possible role of the bacterial flora in adhesive plaster irritation the following additional experiment was carried out.

In 5 patients the type of experiment outlined above was carried out with the hospital and special adhesive tapes. In each patient, two two-inch squares of hospital and special adhesive tape were applied to the flexor surfaces of the forearms. At the end of 7 days, one patient showed a marked erythematous reaction to the hospital adhesive tape. When the plaster causing the reaction was removed, a slimy deposit was seen on its under surface. The irritated skin appeared somewhat macerated and had a distinctly foul odor. Anaerobic cultures were made from the cutaneous surface under one of each of the adhesives including the area of irritation. A positive culture was obtained from the area of irritation only. A Gram positive spore-bearing bacillus, the Corynebacterium and the Bacillus subtilis were isolated.

Two of the four remaining patients could be observed for 7 more days. At the end of that time, one of the patients complained of marked pruritus under the hospital adhesive tape; when the plaster was removed, erythema, edema and induration were found at the site of application. Anaerobic cultures were taken from both patients at the sites of application of the special and hospital adhesives. The anaerobic culture from the patient who had dermatitis showed Micrococcus and Staphylococcus albus while the cultures from the skin under the special adhesive were negative. The other patient, who had shown no reaction to either adhesive, was found to have Sarcina under the special adhesive tape and Staphylococcus albus under the hospital adhesive tape.

In an attempt to evaluate the bactericidal action of the adhesives, optical density studies were made in all instances. Instead of the swab technique for making the original cultures, a platinum spreader was used to obtain the material for culture. At the end of 14 hours, the optical density of the cultures made from under the hospital adhesive in the area of irritation was 0.45. In the second case, which had shown no reaction from either adhesive, the optical density was 0.05 under the hospital adhesive and 0.01 under the special adhesive. This experiment seems to indicate that the bacterial flora does play a role in the irritation produced by adhesive tape.

BACTERIOSTATIC AND BACTERICIDAL EFFECTS OF FATTY ACIDS IN ADHESIVE IRRITATION

If the bacterial flora played an important role in the development of irritation to adhesive plaster, we can only assume that the incorporation of the bacteriostatic and bactericidal agents in the special adhesive explained its relatively low irritating properties. In order to study the role of the fatty acid salts in the prevention of irritation, the following experiments were carried out.

Method

Three patients who had shown reactions to the hospital adhesive served as subjects. One was a patient who, on repeated experiments, showed erythema, edema and vesicles at the end of 24 hours; the other two patients had pruritus, edema and erythema without vesiculation at the end of 48 hours or longer.

The skin of the arm of each of these patients was prepared at one site by the application of a mixture of 15% sodium propionate and 15% sodium caprylate in a carbowax base; at another site the same concentration of the fatty acid salts was applied in alcoholic solution. In this way an attempt was made to study the effects of the fatty acid salts and at the same time to evaluate the possible role of carbowax as a protective non-specific film. The hospital adhesive was then applied over the sites treated with the fatty acid salts and on untreated areas.

Results

At the end of 48 hours there was no reaction over the prepared sites in the 2 cases which had previously shown erythema and edema (but no vesicles). The untreated sites showed the usual reaction of irritation. In the patient with the vesicular reaction, the adhesive plaster had to be removed at the end of 24 hours because of the marked vesicular reaction, both in the areas of skin which had been prepared and in the control sites.

We interpreted this as a demonstration of the action of the fatty acid salts as preventives of adhesive irritation in that type of reaction where bacterial flora played a role in the reaction. In the last case, we were dealing with a probable true reaction of sensitivity to one or more ingredients of the adhesive plaster.

To be absolutely certain of this, we should have been able to demonstrate the specific sensitivity in the patient whose reaction could not be prevented by the application of the fatty acids. In order to approach this problem in another way, we took two patients, one of whom was sensitive to paraphenylendiamine and the other to pyribenzamine hydrochloride. Skin sites were prepared on the arm in each case with the fatty acid ointment and solution as above and patch tests were made with the appropriate sensitizer in each instance. A positive patch test was obtained in the prepared area which in no way differed from the control site.

This was interpreted as a demonstration that the fatty acid salts could in no way prevent a reaction of sensitivity and lent support to the contention that allergic reactions to ingredients of adhesive plaster, once they develop, cannot be influenced by changes in local bacterial flora.

SUMMARY AND CONCLUSIONS

1. A study of the mechanism of adhesive plaster dermatitis was made. The dermatitis produced by two varieties of adhesive tape was compared. One of the adhesive tapes contained zinc propionate and zinc caprylate. It was found that the adhesive tape containing the fatty acid salts showed much less tendency to produce irritation than the one which did not contain such acid salts. In addition, adhesive tape containing fatty acid salts tended to adhere more closely to the skin; it showed less tendency to develop wrinkles; when it was removed, it did not have a slimy deposit on its under surface.

2. Attention was paid to the alterations of pH and of bacterial flora. The pH and the bacterial flora of the surface of the normal skin were studied at the same time.

3. The average pH of the normal skin was 5.2. The pH under the adhesive

giving the greatest irritaton rose to 6.3 at the end of 7 days. At the end of 14 days it was 6.7. Under the adhesive which contained fatty acid salts the pH rose to 5.7 at the end of 7 days and reached 6.4 at the end of 14 days.

4. Under both types of adhesive tape the bacterial flora was altered qualitatively and quantitatively. The decrease in the bacterial flora was especially striking under the adhesive containing the fatty acid salts. When irritation to adhesive tape developed, it could be shown that the numbers of bacteria on the irritated surface were much greater than those on non-irritated areas.

5. Our experiments indicate that the bacteria of the skin surface play a role in the irritation produced by adhesive tape. The incorporation of bactericidal and bacteriostatic agents tends to eliminate the type of adhesive tape irritation in which the bacteria play a role.

6. It could be shown that when the irritation was due to bacteria, it could be prevented by previous treatment of the skin with the fatty acid salts. The irritation could not be prevented if it was due to specific sensitization to ingredients of the adhesive plaster.

7. Adhesive tapes produce three types of irritation:

a. A relatively unimportant fleeting reaction which is most marked in hairy areas and is due to the mechanical trauma of removing the tape. This is the more marked, the more firmly the plaster adheres to the skin.

b. A reaction due to specific sensitivity to one or more of the ingredients of the adhesive tape. This is relatively rare.

c. A reaction due to changes in pH, and to the bacterial flora on the skin surface under the adhesive plaster. This is the most common type. Bacteriostatic and bactericidal agents such as fatty acid salts incorporated in adhesive plaster, can play an important role in preventing this reaction by depressing the bacterial flora.

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