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4th EDITION

CONTACT & OCCUPATIONAL DERMATOLOGY



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JAYPEE

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Chapter 3

Patch Testing

Snapshot

- Allergens and Apparatuses
- Scheduling the Test
- How to Apply the Test
- Patch Test Reading
- Patch Test Interpretation
- Determining Clinical Relevance
- Instruction of Patients in Avoidance of Allergens

Sulzberger and Wise (1931) formally introduced patch testing to the American dermatologic community 85 years ago. The authors presented data on more than 100 patients with eczema in whom this technique was used and identified relevant positive reactions in more than 50% of those tested.

Pearls

- In this condition (eczema, dermatitis) the contact or patch test should be employed, for it, and it alone, can aid in the quest of the etiologic factor and in the study of the dermatitis.

—Sulzberger and Wise, 1931

The technique was initially devised 35 years earlier by Jadassohn. Great strides have been made in our understanding of the mechanisms of allergic contact dermatitis since the early 1900s, and from time to time various in vitro assays have shown promise as methods of detecting sensitivity to contact allergens. Still, the patch test is the only scientific proof of contact allergy.

Pearls

- Properly applied and correctly interpreted patch tests are, at present, the only scientific "proof" of allergic contact dermatitis.

—Fisher, 1986

Despite the high prevalence of allergic contact dermatitis among our patients and the fact that diagnostic patch testing is essential to the care and management of these individuals, this simple bioassay is sorely underutilized. A survey of members of the American Academy of Dermatology revealed that 27% of respondents did not patch test in their practices. Since 58% of members were nonresponders, the percentage of dermatologists who do not patch test is probably even higher and may approach 50%. The percentages of other groups of

clinicians who care for patients with dermatitis, including allergists, occupational medicine physicians, family practitioners, and pediatricians who do not patch test, are certainly even larger.

Pearls

- Education in the technique of patch testing is as essential to physicians in training as is the learning of most surgical procedures.

—Fisher, 1986

Training in the technique is essential to proper use. As in all of medicine, learning is a lifelong continuum. Being trained in the technique of patch testing includes the following:

1. Developing an understanding of the pathophysiology of allergic contact dermatitis.
2. Developing a high index of suspicion for the diagnosis of allergic contact dermatitis so as to properly choose patients to be tested.
3. Learning the technical application of the test: What you need and where to get it, how and when to apply the test, and how to read and interpret the test.
4. Developing expertise in determining the relevance of a positive test result and instruction of the patient in avoidance of the allergen.

As the clinician uses the patch test, he or she becomes more learned in all aspects of the technique. Almost every application of the test is a learning experience for the physician. Although improper usage can lead to both under diagnosis and over diagnosis of contact allergy, each with different and potentially serious consequences, the greatest abuse of patch testing is failure to use the test.

Pearls

- The greatest abuse of patch testing is failure to use the test.

—Colman, 1982

Learning the basics is best accomplished during residency training. If patch testing techniques are not taught during those years, physicians should avail themselves to continuing medical education training courses available through national organizations, particularly the American Contact Dermatitis Society (ACDS) and the American Academy of Dermatology (AAD). The former organization meets annually in conjunction with the AAD and additionally sponsors regional meetings that deal with the scientific and practical aspects of diagnosing and caring for individuals with contact dermatitis. Information about the ACDS can be obtained at ACDS, 2323 North State Street #30, Bunnell, FL 32110 or at their web site—www.contactderm.org.

If courses and scientific meetings are not available to the physician, the basics can be learned through the use of texts, audiovisual materials, and/or Internet webcasts, dealing specifically with patch testing.

This textbook is designed to assist the novice in learning basic techniques, regardless of availability of other materials. Further, it is meant to assist in the ongoing learning process that occurs as the physician uses the technique. The more one tests, the more one learns about allergic contact dermatitis and about patch testing.

Pearls

- Just do it.

—Cher, 1990

Chapters 1 and 2 deal with understanding the pathophysiology of contact dermatitis and choosing the patient to patch test, respectively. This chapter deals with learning the techniques for application and reading of the patch test; this and the following chapters deal with determining the relevance of positive test results and instruction of the patient in avoidance of allergens.

ALLERGENS AND APPARATUSES

To begin patch testing, the clinician needs antigens. The antigens are available in two forms. In the first, they are supplied to the clinician and dispensed in vehicles to be placed in small aluminum chambers (Finn chambers) or other similar chambers (IQ, allergEAZE). This system utilizes antigens in small syringes and dropper bottles and will be referred to as the *Finn Chamber System Test Kit*. It was previously known as the *Allergen Patch Test Kit* (Center Labs). In the second system the antigens are already dispensed in a polymer base (T.R.U.E. Test™ system).

Pearls

- Apparatuses for patch testing include antigens (either T.R.U.E. Test™ or the Finn Chamber System Test Kit), Finn chambers, Scanpor tape, a skin marker, and record sheets.

The T.R.U.E. (Thin-layer Rapid Use Epicutaneous) Test™ system presently consists of 35 common antigens in addition to a negative control. The other system of antigens, the Finn Chamber System Test Kit marketed for the United States, consists of a standard tray of 20 or more antigens. Many more antigens of this type are available in Europe and Canada. Regardless of which system the clinician chooses, Finn chambers and Scanpor tape are needed for testing of nonstandard allergens. In addition, a skin marker and record sheets are needed.

The patch test is a biologic assay fraught with individual variability. All aspects of the test that can be standardized should be. Although other systems for applying the antigens, such as A1-test strips, have been used and antigens can be applied with "Band-Aids" and the like, we strongly recommend use of Finn chambers and Scanpor tape or other similar test systems.

After removal of the patches two readings must be done, one on removal and a second reading 1 or more days later. The application sites are marked so that readings can be done at the later times. The markings must remain visible for the second reading. A number of systems are available to mark the skin, but no marking system is perfect. The two most frequently used are felt-tipped permanent skin markers and fluorescent marking pens. The latter is more cumbersome because it requires a fluorescent light source for reading. On the other hand, the former can be rubbed off and may stain clothing. A marking system is supplied with the T.R.U.E. Test™ system.

A standardized recording sheet should be used for all readings. Such sheets are available with the standard-tray antigens. For other antigens we recommend a homemade six-column

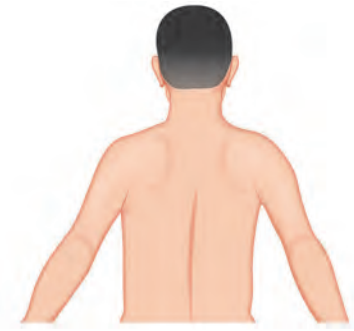
Patch Test Record Sheet

Patient Name: _____

Application Date: _____ 1st Reading Date: _____ 2nd Reading Date: _____

#	Antigen	Morphology reading	Morphology reading	Interpretation	Clinical relevance
		1st Date	2nd Date		
1					
2					
3					
4					
5					
6					

CODES		
Morphology	Interpretation	Clinical relevance
+/-	ALL Allergic	Present
+	? Unknown	Past
++	IRR Irritant	Unknown
+++	– Negative	Not tested
IRR	NT Not tested	
-		
NT		



Application sites

Fig. 3.1: Patch test record sheet.

sheet that can be inserted in the patient's chart (Fig. 3.1). The columns should include the following: (1) number, (2) antigen, (3) first, and (4) second patch test morphology readings, (5) patch-test interpretation, and (6) clinical relevance determination.

In the recent past, professionally prepared allergens have been difficult to obtain in the United States. The Food and Drug Administration has imposed requirements of quality control and proof of efficacy and safety for patch test antigens similar to requirements for marketing of other pharmaceutical agents. This ensures quality antigens for patch testing, but the result of such regulatory oversight has been a paucity of antigens sold in this country because of the high cost of increased premarketing testing and more stringent manufacturing techniques. Presently only the 35-allergen T.R.U.E. Test™ system is FDA approved and available for purchase in the United States (Fig. 3.2). Many other antigens are available from European manufacturers but are not legally sold within the United States. However, the use of such antigens by the clinician to patch test patients in the United States is not illegal.



Fig. 3.2: The T.R.U.E. Test™.
Courtesy: SmartPractice.

Pearls

- Only 35 patch test antigens are sold within the United States. Patch testing with other antigens, however, is not illegal.

Most of the antigens discussed in this book are available from a number of sources. In Chapter 5, we have listed contact information about the major companies that sell these products. Sources for the standard trays for T.R.U.E. Test™ and the Finn Chamber System Test Kit, Finn chambers, Scanpor tape, and marking systems are also listed. These companies frequently have exhibits at national medical society meetings. As an alternative, raw chemicals can be purchased from chemical supply companies and mixed at appropriate concentrations in proper vehicles by a pharmacist or chemist.

Antigen Concentration and Vehicle

The antigens listed in this textbook and sold by the manufacturers listed in Table 3.2 are standardized to concentration and vehicle. Such standardization has generally been achieved from years of testing large numbers of individuals who were allergic to each antigen, as well as individuals who acted as normal controls. The basis of this standardization is an attempt to balance sensitivity and specificity of the biologic assay—the patch test for the given antigen. Using such standard antigens should result in positive test results in the vast majority of allergic individuals and few positive test findings in controls, that is, the fewest false-negative and false-positive results possible for a given allergen. The most common cause for false-positive

responses is irritation. Such reactions are due primarily to the use of too high a concentration of the antigen. Other factors affecting the irritancy of the antigen include the vehicle, occlusion time, and skin integrity.

In addition, the concentrations of the standardized antigens should not actively produce sensitization in tested individuals. It is recommended that the clinician use standardized, commercially available antigens whenever possible. For less common antigens, there are many sources in the literature including the appendix of this text, for determining testing concentrations.

The specific antigens to use for testing in a particular patient depend on the history and the distribution of the eruption. This is called directed or aimed antigen selection. Even the best clinician, however, can be fooled, and the novice is even more likely to choose incorrectly. For this reason, we do not recommend strict directed antigen selection. Our approach is more "shotgun" or tray-selected testing. This usually results in testing larger numbers of antigens. It has been suggested that such testing can increase the incidence of "angry back" or "excited skin syndrome" and false-positive results. We believe that such a risk is greatly outweighed by the increase in the probability of testing to the relevant antigens that could otherwise be missed.

All patients should be tested to a standard series, either the Finn Chamber System Test Kit or the T.R.U.E. Test™. The antigens in those kits are the most frequent agents causing allergic contact dermatitis in the general population in the country where marketed. Frequently, positive reactions are found that do not relate to the present dermatitis (no present relevance) but relate to previous exposures (past relevance). This information given to the patient with proper education about avoidance is important preventive medicine.

Pearls

- All patients should be tested to a standard series.

In addition to the standard series, other trays (preservative and vehicles, cosmetic and fragrances, medicaments, plants, and photoallergens, and miscellaneous trays) should be used when antigens from these broad categories are suspected as relevant from the history or distribution. Chapter 4 should be consulted for selecting trays and additional antigens from the miscellaneous allergen tray to be used in patients with dermatitis of selected distributions. For occupationally suspected allergens, the reader is referred to Chapter 15 for a listing of antigens specific to certain job descriptions. A modified directed antigen selection by the use of trays ensures selection of the etiologic antigen in most cases.

Selected tray testing also increases patient acceptance of patch testing, and increases the likelihood of positive, relevant reactions. The patch testing procedure is time consuming and somewhat uncomfortable for the patient. Increasing the number of antigens tested does not increase the inconvenience or discomfort. Having the patient return on multiple occasions to undergo second or third sets of testing does.

Testing with Nonstandard Antigens

It is sometimes desirable or necessary to test with nonstandard antigens (Table 3.1). These may be pure chemicals but more frequently are complex mixtures from the home, work, or

Table 3.1: Nonstandard allergen testing

Technique	*If Positive*
• Proper dilution	*Controls*: Test 5–10 normal subjects
• Proper vehicle	Test components of mixtures
- Petrolatum	
- Water	
- Alcohol, etc.	

Table 3.2: Testing to nonstandard antigens

Cosmetics and personal care products	
"Leave on": Base makeup, moisturizer, eyes cosmetics, nail polish, lipsticks, sunscreens, colognes, perfumes	As is
"Wash off": Soap, shampoos, cream rinses	1:10-1:100 dilution
Household products: Detergents, bleach, solvents, cleansers	Avoid
Topical Medications	
Antibacterials, eye and ear preparations, corticosteroids	As is
Exceptions: Wart products, anthralin, benzoyl peroxide, tretinoin, known irritants	Consult reference for proper concentration
Industrial products	With care, always use material safety data sheets and references to determine dilution
Clothing, shoes, plants	As is, and soaked with saline or water for 10 minutes. Leave in place for 96 hours.
Unknowns	Never test

recreational environment. Some of these agents can be extremely toxic to the skin and on rare occasions even produce systemic toxic effects on skin exposure. Therefore, such testing, especially with industrial agents, should be undertaken with great care. Never test patients with an unknown substance. Always ask the patient to bring in the manufacturer's list of ingredients for household or personal care products and always obtain material safety data sheets (MSDS) for industrial products (*see* Chapter 13).

Pearls

- Never patch test to unknown substances.

A reasonable rule of thumb in determining how to test to nonstandard antigens is that any agent that is routinely applied to normal skin and left on can be tested "as is," including most cosmetics and personal care products like moisturizers. Products that are routinely diluted in use with water, "wash off products," by rinsing (shampoos, cream rinses, and toothpaste) should be diluted (Table 3.2). Water-soluble products should be diluted in water. Water-insoluble products can be diluted or dispersed in petrolatum (Vaseline) or mineral oil. If a highly

suspect product fails to give a positive result in diluted form, it can be retested at more concentrated dilutions until a positive allergic or irritant test result is obtained. As will be discussed later, irritant and allergic reactions are sometimes difficult to distinguish. If a positive test finding is obtained to a nonstandard antigen, it will be necessary to test 5–10 control subjects with that dilution of nonstandard antigen to rule out a false-positive result due to irritancy. Negative results in controls suggest that the patient's test is a real allergic response.

Household products that do not routinely contact the skin for prolonged periods should be tested in diluted form. Products that are known irritants, like detergents, do not routinely produce allergies and should be tested only in highly suspect situations with much care, or not at all.

Most topical medications can be tested "as is." Some exceptions are irritants like anthralin and wart preparations that contain acids or irritating bases.

If a clothing, shoe, or glove allergy is suspected, a small piece of the material should be removed and soaked in nonpreserved saline or water (not from multiple dose vials) and applied to the skin in a Finn chamber for at least 48 hours. Applications of such products for 96 hours increase the likelihood of obtaining a positive response in an allergic individual.

Pearls

- A positive response to a nonstandard allergen necessitates testing of controls (5–10 individuals) to rule out irritancy.

A positive response to a product or mixture requires testing of components to identify the antigen in the mixture. This testing is unnecessary if the product contains an agent that has produced a positive response when tested in pure form in one of the trays. Components of products for testing can usually be obtained by contacting the manufacturer. Most manufacturers will send small quantities of components; others will send a patch test kit with components appropriately diluted. If not already diluted, each component should be diluted to a concentration comparable to its dilution in the product for "leave-on" agents or a concentration recommended in the literature. Once again, however, wash-off products and known irritants must be further diluted to avoid irritant responses.

SCHEDULING THE TEST

Once the patient has been selected for testing and the antigens have been chosen, an appointment is made for the test application. Testing can be done at the initial visit, but often it is scheduled for a later time. The delay may be necessary to avoid false-negative or false-positive results, to prepare the patient properly, or to schedule readings conveniently.

The following rules should be followed when possible:

1. *Do not test when dermatitis is acute and/or severe*. Such testing can result in "angry back" or "excited skin" reactions, which are false-positive responses. It can also lead to a significant worsening of the patient's disease. It may be impossible to patch test in a patient until sufficient area of the back is clear for patch application.
2. *Do not test if the patient is taking systemic corticosteroids*. Although it is frequently stated that testing can be done as long as the patient is taking less than 20 or 30 mg/day of

prednisone or equivalent doses of another corticosteroid, it is always preferable to test a patient at least 1 week after discontinuation of treatment with these agents. Occasionally, of course, testing during such therapy will be necessary. It should always be remembered that under such circumstances false-negative results can occur and relevant allergens can be missed. Systemic antihistamine therapy does not interfere with testing unless contact urticaria is suspected. Topical corticosteroid application to the back should be discontinued for at least a week before tests are applied. A recent sunburn to the back 1 to 2 weeks before testing can, as with topical corticosteroids, lead to false-negative results.

3. *Patch tests must be removed and read at* 2 *days and a second, delayed time from* 3 *to* 7 *days after initial application*. Tests should be applied only when such a schedule is convenient for the patient and physician.
4. *Patch tests should not be applied if the patient is going to perform activities that result in loosening of the patch tests*. The patient must be instructed that he or she will not be able to shower or bathe their back until the final reading. The back must be kept dry for the additional period after patch removal until the final reading. Outdoor laborers may have to schedule testing during days off. Patients planning social functions may have to schedule at more convenient times. Patient with hairy backs should be instructed to have a family member shave the back 48 hours before patch test application. This should not be done in the office on the day of application because shaving may lead to irritation and false-positive responses.

Pearls

- Your doctor believes that your skin disease may be related to contact with chemicals in your environment. This is called allergic contact dermatitis.
- The only way to obtain proof of allergic contact dermatitis is by patch testing. This is different from scratch or prick testing and does not identify food or inhalant allergies or allergies to oral medications.
- Chemicals will be taped to your back in small chambers. The skin will not be broken. The "patches" stay in place for 48 hours. You cannot shower or do any work or exercise that will wet or loosen the patches.
- The "patches" will be removed, and a reading will be done after 2 days. The patch sites will be marked, and you will be asked to return for a final reading on another day. Between the two readings you can bathe, but you may not wash your back.
- You may develop itching under the patches. If it becomes very severe or if you develop pain, you should try to reach your physician. If he is unavailable, have someone carefully remove the painful patch. Try not to disturb the other patches.
- You may develop blisters at positive sites, and very rarely prolonged reactions or even scars may develop at such sites.
- You will be tested for your response to common chemicals. If you believe that your problem is worsened by any agent or product, even a medication, please bring it with you (and the container with the ingredient list) when you return for testing.
- You should not be tested if you are taking cortisone pills, have had a cortisone injection, are applying cortisone to your back, or have had sun exposure on your back recently. Please tell the doctor if any of these have occurred. Please tell the doctor if you are pregnant. Please call if you have any problems. Please ask if you have any questions.
- Your tests may be completely negative. This probably means that an allergy is not the cause of your skin problem. The test is not infallible, however, and an allergy may be missed. Retesting in the future may be indicated.

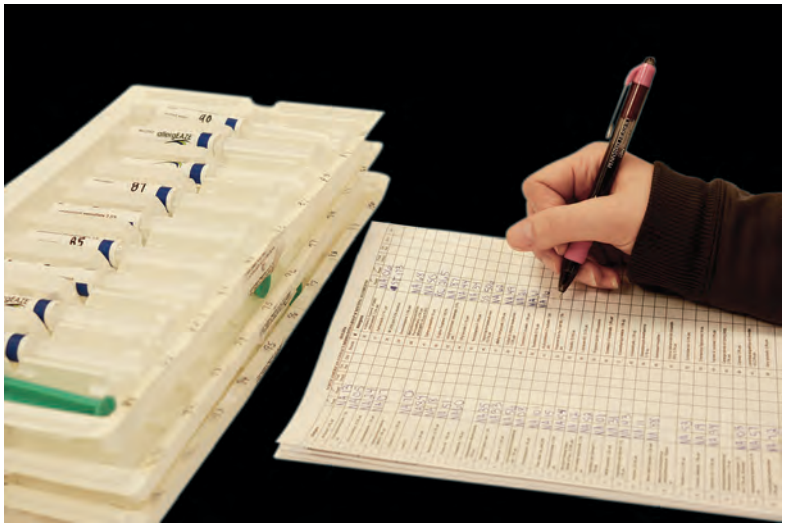


Fig. 3.3: A patient information sheet to be used when recording a patch test.

5. *Patch testing of the standard, delayed type should not be done in a patient who gives a history of an immediate urticarial type of disease.* Such patients could suffer a generalized urticarial response or even anaphylaxis with routine testing. Such patients should be tested as outlined in Chapter 16, with the assistance of an allergist.

Scheduling the patient for testing and informing the patient about the purpose and limitations of testing can be done by the physician or nurse-technician and can be assisted by a written information sheet. Recording the results of testing should be done on a standardize recording sheet as seen in Figure 3.3.

HOW TO APPLY THE TEST

Finn Chamber System

Finn chambers are supplied in strips of 10 chambers on tape—two parallel rows of 5 chambers. The backing is removed and antigens are applied to the disks. The disks are then applied to the upper portion of the back. Each physician or nurse technician who applies patch tests develops a style that allows quick and reproducible application. A few points to remember are listed as follows:

1. Layout, with backing removed, all the chambers to be used. You may wish to place them on Scanpor tape (Fig. 3.4).
2. Starting with number 1 of the standard tray, apply a small amount of antigen to each disk. A 5-mm ribbon of petrolatum-based antigen is sufficient (Fig. 3.5). Proceed in sequence through the trays to be tested.
3. For liquid antigens, place a filter paper disk in the chamber, and apply one drop of liquid, just sufficient to soak the disk (Figs. 3.6 and 3.7). Petrolatum patches can be made up a few hours in advance; liquid patches should be made up immediately before applying.

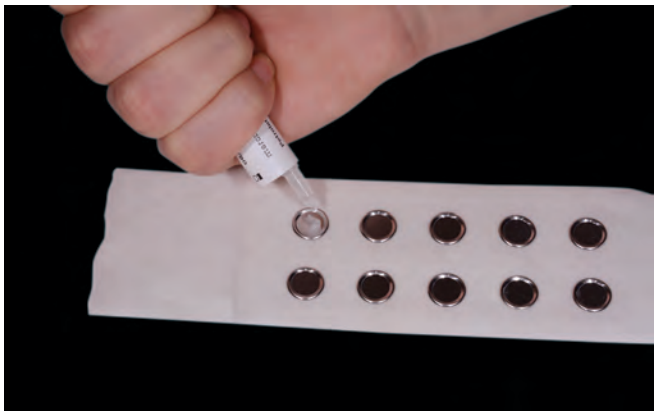


Fig. 3.4: Finn chambers laid out on Scanpor tape.



Fig. 3.5: A 5-mm ribbon of petrolatum-based allergen is placed into the Finn chamber.

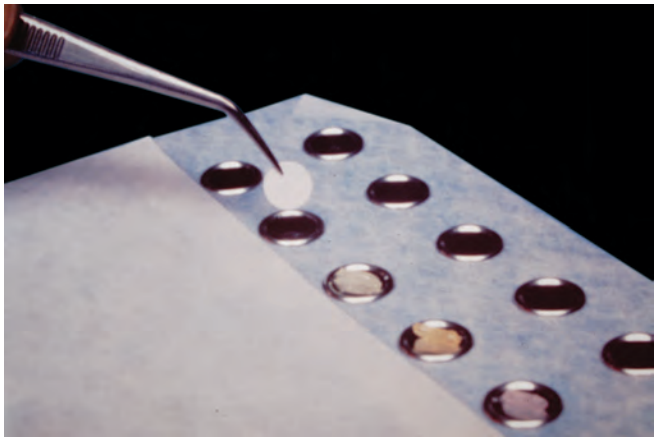


Fig. 3.6: Application of a filter paper disk into the Finn chamber to hold liquid allergens. *Courtesy*: Hermal Pharmaceutical Laboratories.

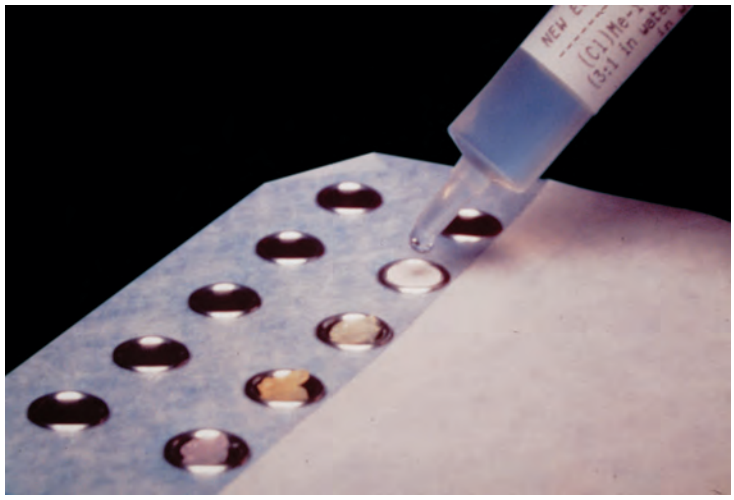


Fig. 3.7: One drop of water-based allergen placed into the Finn chamber containing the filter disk. *Courtesy*: Hermal Pharmaceutical Laboratories.

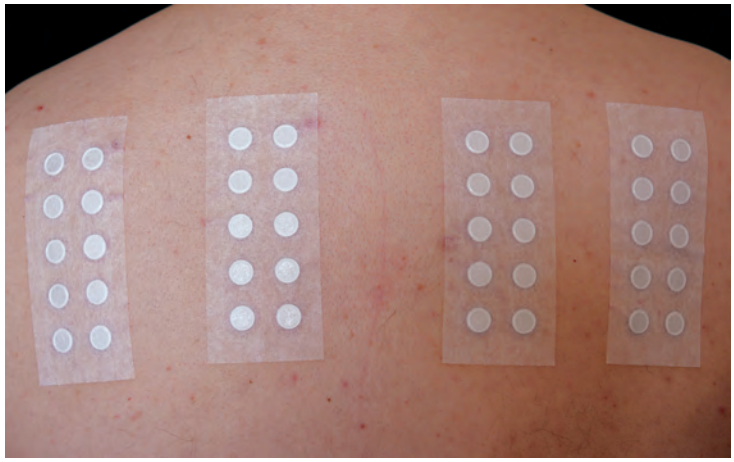


Fig. 3.8: Finn chambers with allergens applied to the upper back.

Pearls

- Patch testing a patient taking systemic corticosteroids or one who has recently applied topical corticosteroids to the patch test application test sites can result in false-negative reactions. Systemic antihistamine therapy has no effect of delayed patch test results.

4. Remember that when applied to the back, the order of the antigens is left to right reversed, that is, the antigens applied to the chambers (as they are laid out) on your far left are applied to the far right of the patient's back. Thus it is best to apply the first antigen to the first disk on the first row on your left (Fig. 3.8). Apply additional Scanpor tape to secure the patches (Fig. 3.9).

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CONTACT & OCCUPATIONAL DERMATOLOGY

Contact and Occupational Dermatology is an introductory text for physicians who patch test. It is 'user-friendly' providing the clinician with a logical approach to the evaluation and the care of patients with contact or occupational dermatitis.

The approach to the contact dermatitis patient should be similar to the organization of this text:

- Obtain a thorough history and perform a skin examination
- Patch test with trays of allergens based on history, distribution of dermatitis, and occupation
- Give allergen exposure and Contact Allergen Management Program (CAMP) lists to patients
- Manage with appropriate therapy and prevention.



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