

Patch-Testing North American Lip Dermatitis Patients: Data from the North American Contact Dermatitis Group, 2001 to 2004

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Background: The most common differential diagnoses for patients presenting with lip dermatitis or inflammation include atopic, allergic, and irritant contact dermatitis. Patch testing can be performed to identify the allergic contact conditions.

Objective: To report North American Contact Dermatitis Group (NACDG) patch-test results of patients who presented for patch testing with only lip involvement from 2001 to 2004. Patient characteristics, allergen frequencies, relevance, final diagnoses, and relevant allergic sources not in the NACDG screening series were evaluated.

Methods: The NACDG 2001–2004 database was used to select patients presenting with only lip involvement.

Results: Of 10,061 patients tested, 2% ($n = 196$) had lips as the sole involved site. Most (84.2%) were women. After patch testing, 38.3% ($n = 75$) were diagnosed with allergic contact cheilitis. Fragrance mix, *Myroxylon pereirae*, and nickel were the most common relevant allergens. Of 75 patients, 27 (36%) had relevant positive patch-test reactions to items not on the NACDG series; lipstick and cosmetics were the predominant sources.

Conclusions: Patch testing is valuable in the evaluation and identification of contact allergy in patients referred for lip dermatitis. The use of supplementary allergens based on history and exposure is important in the identification of additional relevant allergens. Over a third of patients with contact allergy had other factors, such as irritant dermatitis, considered relevant to their condition.

CONTACT CHEILITIS is an inflammatory condition of the lips that can manifest as itching, burning, dryness, erythema, fissuring, crusting, and edema.¹ Factors contributing to this condition may be endogenous to the individual (atopic diathesis), exogenous to the individual (including allergens and irritants), or both endogenous and exogenous. Contact cheilitis can develop as a primary disorder of the vermilion or may arise as an extension from nearby skin or from the oral mucosa.² The unkeratinized (mucocutaneous) epithelium of the vermilion is more susceptible to allergy than is the oral mucosa, perhaps because of the buffering and solvent actions of saliva. Therefore, if both the oral mucosa and the lips are exposed to an allergen, cheilitis will often be the sole manifestation.^{1,3} Allergic contact cheilitis (ACC) has been reported to result from the use of a wide array of materials, including cosmetics (lipsticks, lip balms, makeup), moisturizers, sunscreens, nail products, oral hygiene products

(mouthwashes, toothpastes, dental floss), dental appliances, foods, and metals.^{1,4–6}

Studies that report the patch-test results of patients presenting with cheilitis have been conducted in the United Kingdom,⁷ Italy,⁴ Singapore,² Australia,⁸ and India.⁹ The purpose of this study was to analyze the data collected by the North American Contact Dermatitis Group (NACDG) from 2001 to 2004 and to report its findings on patient characteristics and allergen frequency in patients presenting solely with lip involvement.

Materials and Methods

The NACDG data were compiled from 13 clinics in North America. De-identified data were entered into a computerized database (*Access 2003*, Microsoft Corporation, Redmond, WA) from 2001 to 2004. Data for this study were entered into a database (*SPSS version 14*, SPSS Inc., Chicago, IL) for analysis. This database was used to identify patients with the location of “lips” as the sole area of involvement upon presentation for patch testing.

All patients were patch-tested with the NACDG series of 65 allergens in addition to other allergens deemed

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potentially relevant by the individual clinician. Patch tests and readings were performed in accordance with standard NACDG practice.¹⁰ From the 2001–2002 series to the 2003–2004 series, six allergens differed, resulting in a total of 71 allergens in the 4-year period.¹⁰ The source of a supplemental allergen that was not in the screening series was noted when applicable. Whether the source was a specific allergen or a patient's personal product was not indicated. Only one relevant non-NACDG allergen source could be recorded.

The relevance of each NACDG allergen was recorded as definite, probable, possible, past, unknown, or not relevant.¹⁰ For the purposes of this study, clinical relevance was defined as present relevance (definite, probable, or possible) unless otherwise stated. The atopic markers (a history of atopic eczema, asthma, or hay fever/allergic rhinitis) were recorded. An atopic predisposition was defined as the presence of at least one of these three markers.

To ensure that only patients identified with contact allergy by patch testing were included in the further analysis of allergens and sources, the following criteria were required for a diagnosis of ACC: (1) final interpretation of at least one patch-tested allergen coded as allergic; (2) at least one code for final diagnosis of contact allergy entered on the data form; and (3) clinical relevance coded as possible, probable, or definite, *or* allergy to a non-NACDG allergen (either the patient's own product or a supplemental allergen) with a recorded known source. If a patient's data fit the above criteria, the patient was defined as having a clinically relevant allergy (ie, ACC) for the purposes of this study.

On T.R.U.E. Test allergen panels 1.1 and 2.1 (Allerderm, Phoenix, AZ), there are 23 allergen patches, some of which are mixtures. We determined an allergen on the NACDG series to be present in the T.R.U.E. Test if it was listed as a component of a mixture or as an individual allergen. This is similar to the methodology used by Saripalli and colleagues.¹¹ For example; cinnamic aldehyde is a separate allergen on the NACDG series, but it is included in the fragrance mix in the T.R.U.E. Test series; hence, we considered it as present in the T.R.U.E. Test. Patients fulfilling the above criteria for clinically relevant allergy were stratified into the following three groups to hypothetically determine if their allergies could be detected by the T.R.U.E. Test: (1) patients who reacted solely to those NACDG allergens that were also present on T.R.U.E. Test panels 1.1 and 1.2, (2) patients who reacted only to NACDG allergens not present in the T.R.U.E. Test, and (3) patients who fit the criteria for both of the above groups.

After patch testing was completed, the NACDG investigator determined and recorded one to three post-patch-test "final" clinical diagnoses. Recorded clinical diagnoses included allergic contact dermatitis, irritant contact dermatitis, atopic dermatitis, other dermatitis, contact urticaria, and other dermatoses. The categories "other dermatitis" or "other dermatosis" were used at the discretion of each investigator. An informal survey of NACDG members revealed that the "other dermatoses" category included lichen planus, rosacea, and burning mouth syndrome. The "other dermatitis" category included unknown causes of dermatitis.

Results

Demographics

Of 10,061 patients patch-tested from 2001 to 2004 by the NACDG, 196 patients (2%) were identified with a skin condition limited to the lips. The average age was 46.5 years (range, 9–83 years). Females accounted for 84.2% of the population ($n = 165$); males accounted for 15.8% ($n = 31$). The population was largely Caucasian (87.8%, $n = 172$); other ethnic groups represented were African (6.2%, $n = 12$), Asian (3.1%, $n = 6$), and Hispanic (2.6%, $n = 5$). Seventy-three patients (37.2%) had at least one manifestation of the atopic triad by a history of atopic eczema, hay fever, or asthma. Seventy-five patients fulfilled our selection criteria for ACC. The age range was the same as that of the population presenting with lip dermatitis (mean, 48.7 years). Males accounted for 8% ($n = 6$) of the subset with ACC, and females accounted for 92% ($n = 69$). Fewer patients in the ACC subgroup were atopic (28%, $n = 21$) compared to all patients with lip dermatitis. Patients with a history of at least one of the atopic markers accounted for 38.7% ($n = 3,892$) of the general patch-test population.

Patch-Test Results and Relevance

Of the 196 patients having the site code "lips," 75 (38.3%) fit our selection criteria for ACC. Eighty percent of the 75 patients ($n = 60$) had at least one clinically relevant positive patch-test reaction to an allergen on the NACDG series. Sixty-four percent ($n = 48$) had a positive patch-test reaction to only an allergen on the NACDG series, and 16% of patients ($n = 12$) had a relevant positive patch-test reaction to both an NACDG series allergen and another relevant allergen (either a personal product or a supple-

mentary allergen). Among the 60 patients with a positive patch-test reaction to an NACDG series allergen, a total of 127 positive allergic patch-test reactions were coded as relevant. Of these, 2.4% were coded as definite clinical relevance ($n = 3$), 33.1% were considered as probable clinical relevance ($n = 42$), and 64.6% were coded as possible clinical relevance ($n = 82$). Twenty-seven patients had a positive patch-test reaction to a supplementary allergen (either a personal product or a selected allergen not in the NACDG series), and 15 of these patients were allergic only to the supplemental non-NACDG allergen (Fig 1).

Allergen Frequencies and Sources

The clinically relevant positive patch-test reactions to the NACDG standard tray allergens are reported in Table 1. Fragrance mix was the most common allergen (2 reactions of probable relevance and 16 of possible clinical relevance), followed by *Myroxilon pereirae* (balsam of Peru) (2

probable and 12 possible clinical relevance) and nickel sulfate (1 definite, 4 probable, and 8 possible clinical relevance [$n = 13$]). The main sources of fragrance were oral hygiene products ($n = 6$), cosmetics ($n = 3$), and lipsticks ($n = 3$). The sources of *Myroxilon pereirae* included cosmetics ($n = 4$), lipsticks ($n = 3$), and oral hygiene products ($n = 3$); one case was attributed to food. The most common source of clinically relevant nickel allergy was jewelry ($n = 7$); there were also two cases associated with tools and one case each associated, respectively, with an unspecified medical health device, amalgam, and a musical instrument.

Cosmetics (including makeup and lipstick) were the most common sources of reactions of present relevance among the 60 patients with at least one clinically relevant positive patch-test reaction to an allergen in the NACDG series. Cosmetics, makeup, and lipstick accounted for 39 of 110 recorded known sources of exposure to allergens (35.5% of all recorded sources). Less common sources included jewelry (16 of 110 [14.5%]), medicaments (neomycin, bacitracin, budesonide and tetracaine, 14 of 110 [12.7%]), and oral hygiene products (12 of 110 [10.9%]). Some patients had more than one relevant positive reaction and thus had more than one source coded for their allergic reactions. Twenty-seven patients were identified as allergic to an allergen not included in the NACDG series. The most common exposure source in the non-NACDG series relevant-allergen category was again cosmetic products (including makeup) (10 of 27 [37.0%]). The second most common source was lipstick (25.9%, $n = 7$), followed by moisturizers, lotions, and creams (14.8%, $n = 4$). One patient each had an allergic reaction to a medication, an oral hygiene product, a dentistry product, or artificial nails (Table 2).

T.R.U.E. Test Results

Of the 60 patients with clinically relevant positive patch-test reactions to NACDG allergens, 53.3% could hypothetically have had all allergens detected by T.R.U.E. Test panels 1.1 and 1.2 ($n = 32$). Thirty-three percent would have had at least one allergen (but not all allergens) detected by the T.R.U.E. Test ($n = 20$), and 13.3% would have had none of the relevant positive NACDG series allergens detected if the T.R.U.E. Test had been used alone ($n = 8$). However, use of the NACDG allergen series alone did not detect the supplementary non-NACDG allergens that were identified for 27 patients.

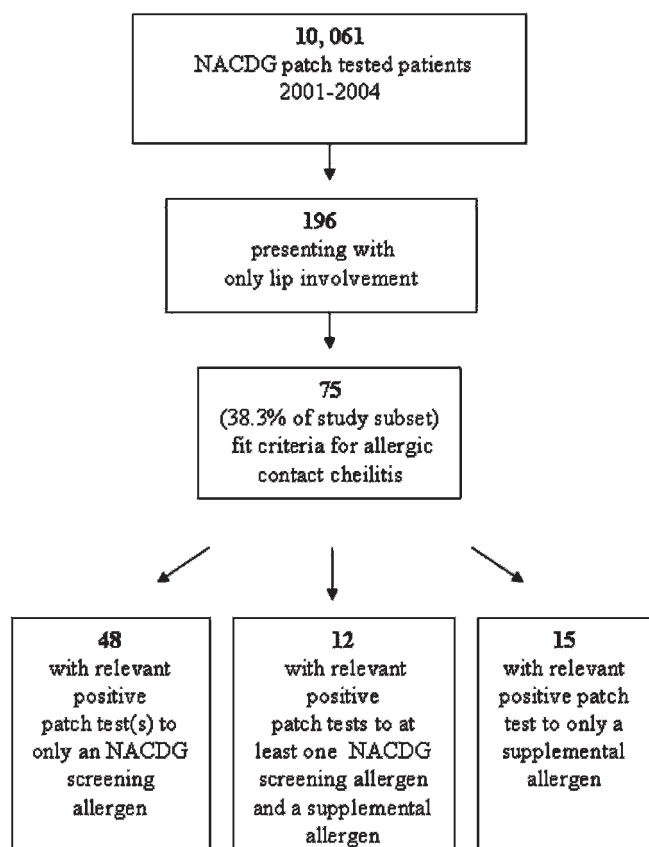


Figure 1. Flow diagram of patch-tested patients with lip-only involvement. (NACDG = North American Contact Dermatitis Group)

Table 1. Allergens Identified in 60 Patients with Clinically Relevant Positive Patch-Test Reactions to NACDG* Series Allergens

Allergen	Patients with ACC (%)	No. of Reactions [†]
Fragrance mix 8% pet	30.0	18
<i>Myroxilon pereirae</i> (balsam of Peru) 25% pet	23.3	14
Nickel sulfate 2.5% pet	21.7	13
Sodium gold thiosulfate 0.5% pet	13.3	8
Neomycin sulfate 20% pet	11.7	7
Cobalt chloride 1% pet	10.0	6
Propylene glycol 30% aq	8.3	5
Lanolin alcohol 30% pet	6.7	4
Cinnamic aldehyde 1% pet	6.7	4
Bacitracin 20% pet	5.0	3
Benzophenone-3 3% pet	5.0	3
Methyldibromoglutaronitrile/phenoxyethanol 2% pet	5.0	3
Tea tree oil, oxidized, 5% pet	5.0	3
Budesonide 0.01% pet	5.0	3
Mercaptobenzothiazole 1% pet	3.3	2
Formaldehyde 1% aq	3.3	2
Potassium dichromate 0.25% pet	3.3	2
Tosylamide formaldehyde resin 10% pet	3.3	2

ACC = allergic contact cheilitis; aq = aqueous; pet = petrolatum.

*North American Contact Dermatitis Group.

[†]In addition to the reactions listed in this column, there was one reaction to each of the following: colophony, p-phenylenediamine, carba mix, thiuram mix, ethylenediamine dihydrochloride, quaternium-15, mercapto mix, dimethylol dimethyl hydantoin, methylchloroisothiazolinone/methylisothiazolinone, 2-bromo-2-nitropropane-1,3-diol, chloroxylenol, diazolidinylurea, ethyleneurea/melamine formaldehyde, iodopropynyl butyl carbamate, dl- α -tocopherol, ethyl acrylate, methylmethacrylate, tetracaine, cocamidopropyl betaine, Compositae mix ylang ylang oil.

Post-test Final Diagnoses

Of the selected group of 75 patients fitting the criteria for ACC, 65.3% ($n = 49$) had a sole final diagnosis of contact allergy and 34.7% ($n = 26$) had at least one additional diagnosis recorded. Just over a third of patients with allergic contact dermatitis had additional factors contributing to their condition. The second most common diagnosis after allergic contact dermatitis was irritant dermatitis. Irritant contact dermatitis was listed as a component of the final diagnosis for 28% of patients

($n = 21$). Irritant dermatitis was followed by other dermatitis ($n = 4$); contact urticaria, other dermatosis, and atopy were included in the final diagnosis of one patient each.

Discussion

Females accounted for 84.2% of patch-tested patients with only lip involvement, which is in accordance with other studies on ACC that report a range of 70.7 to 90% female patients.^{2,4,8} Female predominance may be explained by

Table 2. Sources of Allergic Contact Cheilitis in 27 Patients with Relevant Non-NACDG Screening Allergens

Source	% of Total Reactions	No. of Reacting Patients
Lipsticks	25.9	7
Makeup	18.5	5
Cosmetics; skin or health care products	18.5	5
Moisturizers, lotions, or creams	14.8	4
Sunscreens	7.4	2
Oral hygiene products	7.4	1
Dentistry products	3.7	1
Artificial nails	3.7	1
Topical medications	3.7	1

the presumption that women wear more cosmetics and lip products than men and are also more likely to seek medical attention for a process affecting physical appearance.⁴

Relevant Allergen Frequencies

Strauss and Orton,⁷ Zoli and colleagues,⁴ and Lim and Goh² reported fragrance mix as the most common cause of allergy in patch-tested patients with cheilitis. The fragrance mix used by the NACDG is composed of eight chemicals: cinnamic aldehyde, cinnamic alcohol, hydroxycitronellal, amylcinnamaldehyde, geraniol, eugenol, isoeugenol, and oak moss absolute. These ingredients may be found in products ranging from toothpastes, mouthwashes, bubble gums, dental impression compounds, cosmetics, perfumes, soaps, and flavorings in foods.¹ The main sources recorded for fragrance allergy in our study were oral hygiene products, followed by cosmetics and makeup and then by lipsticks. *Myroxilon pereirae* (balsam of Peru) was also a cause of frequently relevant positive patch-test reactions. The recorded sources of *Myroxilon pereirae* were similar to those of fragrance mix. Nickel yielded 21.7% of all clinically relevant positive reactions. Nickel allergy is extremely common in the general population; NACDG data from the 2001–2002 study period revealed that 17% of patch-tested patients had positive reactions to nickel.¹⁰ Nickel was also one of the most common sensitizers (in addition to fragrance) in a study by Zoli and colleagues of patch-tested patients with cheilitis and perioral dermatitis.⁴ In that study, four patients with relevant nickel allergy were treated successfully by cessation of their lip cosmetics, which the authors stated may have contained trace amounts of nickel.^{4,12} Makeup or lipstick containers are another possible source of occult nickel exposure. Several other studies reported nickel as a less relevant allergen in cheilitis, accounting for only 5 to 9% of positive patch-test reactions.^{2,7,8} The primary source recorded for relevant nickel allergy in our population was jewelry. Nickel is a known cause of ectopic dermatitis of the eyelids; it is possible that other areas of the face, such as the lips, may exhibit ectopic reactions.

In contrast to the general patch-test population, patients with only lip involvement had very few positive patch-test reactions to preservatives. In the overall NACDG patch-test population from 2003 to 2004, quaternium-15 ranked as the fifth most frequently positive patch-test allergen; its prevalence rate among all tested patients was 8.9%.¹⁰ A likely explanation for this difference may be the formulation of lip products. Most lip products are anhydrous and are largely composed of waxes, oils,

pigments, and emollients. Bacterial growth, although possible, is of less concern in a water-free mixture; hence, fewer preservatives and lower concentrations are used.

Allergen Sources

Overall, the most common sources of allergic reactions to NACDG allergens as well as to personal products or other supplementary allergens were cosmetics (including makeup and lipstick). This is consistent with most major reviews.^{2,4,7} Lipstick was coded as the source of 17 positive reactions in our group of 75 patients with ACC, less than that reported in studies by Lim and Goh² and by Strauss and Orton,⁷ who found lip products to account for 50% or more of ACC cases. This discrepancy may be explained by the possibility that NACDG investigators included lipstick in a broader cosmetic category instead of coding it more specifically, especially since there is no explicit code for additional lip products such as glosses or balms. After jewelry, the next most common sources of allergy in our series were medicaments (neomycin, bacitracin, budesonide, and tetracaine) and oral hygiene products.

Other studies of cheilitis have noted similar common sources and allergens. Lim and Goh studied 202 patients presenting with cheilitis. The most common source of ACC was cosmetics (58%), followed by toothpastes (29%), medicaments (7%), and nickel (6%).² In Francalanci and colleagues' study of ACC, 15 patients were allergic to toothpaste; the majority of sensitizations were due to flavoring substances.⁶ The authors suggested that perhaps ACC from toothpaste is underestimated because many toothpaste flavorings (including peppermint, spearmint, carvone, and anethole) are not found in a standard screening series of allergens. In 1999, Freeman and Stephens reported cosmetics and medicaments as the most common sources in their study of 75 patients (24% of patients were allergic), followed by toothpastes and sunscreens (14%).⁸ Zoli and colleagues, in 2006, reported the most common relevant allergens as nickel and fragrance mix (4 of 27 [14%] relevant positive patch-test reactions), followed by *Myroxilon pereirae* and methyl-di-bromoglutaronitrile (Euxyl K400) (3 of 27 [11%]).⁴

Screening Series Performance

There is concern in the dermatology community about the effectiveness of the allergens approved in the United States by the Food and Drug Administration for detecting important relevant allergens, especially in certain populations (such as referral patients, patients with persistent

dermatitis despite testing, or patients in particular occupations). In 2003, Saripalli and colleagues examined the use of the T.R.U.E. Test in a retrospective review of 898 patch-test patients, a subset of the NACDG database.¹¹ The T.R.U.E. Test was better at detecting clinically relevant positive patch-test reactions in our patients with cheilitis than in that general patch-test population; 53.3% of patients with positive patch-test reactions deemed currently relevant would have had all their potential allergens detected, 33.3% of patients would have had some of their allergens detected, and 13.3% of patients would have had none of their allergens detected. These high rates are likely because ACC in our population was most often related to fragrance, *Myroxylon pereirae*, and nickel, all components of the T.R.U.E. Test. However, the NACDG series alone also would have failed to identify 27 patients with other positive reactions to relevant supplementary allergens.

Less Commonly Reported Causes of ACC

Strauss and Orton, using an extended cosmetic-vehicle/lipstick series, detected 32% of patients with allergy who would not have been detected with their standard series.⁷ Other reported potential causes of ACC that are not routinely tested by the NACDG series and that are more elusive suspects include fruits, flavorings, herbs and spices (such as spearmint oil), anethole,¹³ carvone,¹⁴ vanilla,¹⁵ rosemary,¹⁶ garlic,¹⁷ geraniol,¹⁸ kiwi fruit, and cigarette paper.⁵ In toothpastes, allergens reported in addition to mint flavorings include sodium laurel sulfate¹⁹ and cocamidopropyl betaine,²⁰ which is included in the NACDG series. In lipsticks and glosses, some uncommon reported allergens have included octyl gallate,²¹ propyl gallate,²² ricinoleic acid,²³ D & C red no. 7,²⁴ isopalmityl diglyceryl sebacate,²⁵ glyceryl monoisostearate monomyristate,²⁶ and diisostearyl malate.²⁷ Other reported allergens include mandelic acid,²⁸ shellac,²⁹ beeswax,³⁰ castor oil,³¹ and pentaerythritol rosinat³² (an ester gum derived from rosin and pentaerythritol in cosmetics).³³

Study Limitations

The patients tested by the NACDG were overwhelmingly a referral population, and some of them had been tested with the T.R.U.E. Test prior to referral. The application of these results to a general dermatology setting may be limited. Untested allergens may have been important. Essential to the definition of possible relevance is that circumstances exist that could *possibly* lead to exposure;

therefore, the reporting of possible relevance is limited by the investigator's and patient's knowledge of possible exposures. This is a relevance estimate; the definition may lead to an overestimation of positive allergen relevance. A more exacting and better measure of relevance is difficult in this type of primarily referral population. It would require follow-up over time to confirm whether improvement or clearing resulted from the avoidance of a particular allergen. In many NACDG cases, this is not practical.

Conclusion

It is not uncommon to have more than one factor contributing to cheilitis (for example, atopic diathesis and allergy, or allergic and irritant dermatitis). Notably, just over one-third of patients with allergic cheilitis also had another condition contributing to their dermatitis.

Cheilitis is a complex problem that can be attributed to a number of factors and hence requires a detailed exposure history. The history should include a review of atopic diathesis, lip licking, and potential contactants such as cosmetics (especially lipsticks, balms, and glosses) and moisturizers. Also pertinent to the exposure history may be sunscreens, jewelry, recent dental procedures, dental appliances and amalgams, oral hygiene products (such as toothpastes, mouthwashes, and gums), musical instruments, foods, spices, and flaring factors perceived by the patient.

Scrutinizing this data analysis, we noted that identification of clinically relevant positive allergens is higher in the overall patch-tested population (50.7%, $n = 5,096$) than in this lip-only subgroup. The fact that 38.3% of patients referred for this problem are identified with relevant contact allergies suggests the following: (1) it may be more difficult to predict or determine, based on history and examination, which patients in this group are better candidates for patch testing; and/or (2) a broader selection of suspect supplementary allergens, including the patients' own products (especially lip products) and food and oral hygiene products, is critical to identifying relevant allergens.

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