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The use of chemical probes to assess the facial reactivity of women, comparing their self-perception of sensitive skin

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Synopsis

"Sensitive skin" is a term that has a very distinct meaning to each individual, but over a large group the definition may vary considerably. In this study approximately 1000 Caucasian females (ages 18 to 65) in five geographically diverse locations (Arizona, Ohio, New Jersey, Manitoba, and Florida) were recruited to answer a questionnaire that specifically asked, "Do you have sensitive skin?" and also documented dermatological parameters and reactions to products. Three chemical probes were applied to each volunteer on separate visits to the laboratory: 10% aqueous lactic acid, 10% balsam of Peru, and 10:90 chloroform/methanol. Burning/stinging responses were recorded each minute for up to ten minutes. The endpoints for analysis were (a) time in minutes for perceived burning/stinging and (b) maximum score achieved. The study was undertaken to compare individuals who classified themselves on a written questionnaire as having sensitive skin with a group of individuals self-classified as having non-sensitive skin. The response parameters for each of the chemical probes were correlated with the subject's self-assessment of sensitive skin condition, skin medical history, and tendencies for personal care product selection. With each of the chemical probes, a statistically significant difference was found between the responsiveness of the self-assessed sensitive skin and non-sensitive skin groups for the parameters measured (time to perceived burning/stinging and maximum score achieved). However, there were a large number of subjects self-perceived as sensitive who did not respond to any of the chemical probes, while others self-perceived as non-sensitive responded strongly. Analysis of demographic and response data did not identify any specific profile of responders and non-responders. These results indicate that individual perception of sensitive skin by self-assessment may not always conform to the functional determination of sensitivity to chemical probes.

INTRODUCTION

When normal adult American women are asked whether they have sensitive skin, a large

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proportion respond positively. Producers of skin care products are well aware that many women report that they are intolerant to a variety of cosmetic formulations, citing sunscreens, fragrances, and moisturizers as most often troublesome. By "sensitive skin" some respondents mean any adverse event including various rashes, breakouts, and assorted visible dermatoses, mainly focused on the face (1). A sizeable number of women with self-assessed "sensitive skin" record a variety of purely subjective discomforts that occur in the absence of clinical signs. These include stinging, burning, itching, tightness, and other vague sensations.

The question arises regarding the credibility of these assessments, especially the subclinical neurosensory reactions. Among the pressing issues are: Can women with sensitive skin be identified by clinical examinations? Is there a recognizable phenotype such as oily, dry, or photodamaged skin? What tests are available to validate the presence of sensitive skin? Should pre-marketing surveys of new skin care products be carried out in panels of women who have been objectively identified as having sensitive skin?

We examined the sensitivity of chemical probes to assess the prevalence and severity of sensitive skin.

MATERIALS AND METHODS

Approximately 1000 adult white females (ages 18 to 65) were recruited from five geographically diverse locations in the North American continent: Arizona, Ohio, New Jersey, Manitoba, and Florida. This study compared the responses of two populations who by self-assessments perceived themselves to have sensitive or non-sensitive skin to three chemical probes, each of which elicited characteristic reactions. In each test site approximately 200 women participated, 40% of whom had sensitive skin while 60% were non-sensitive. There was an attempt to enroll 50% from each group.

At the first visit each subject answered a 20-item questionnaire that specifically asked, "Do you have sensitive skin?" and gave a detailed account of adverse reactions to facial skin care products. Applications of the chemical probes were randomized to opposite sides of the face. There were three visits at least two days apart, with one probe being applied at one time.

The three chemical probes were applied on separate visits in accordance with the methods outlined below see (Figure 1). A script was provided to standardize the wording used when communicating with the subjects regarding subjective responses. Burning/stinging responses were recorded each minute for up to ten minutes, utilizing the following grading scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe. The endpoints for analysis were (a) time in minutes to perceived burning/stinging and (b) maximum score achieved.

STATISTICAL ANALYSIS

The data used in the statistical analysis were the times to perceive the specified sensory response and the maximum score achieved. Student's t-test was used to establish whether there were statistically significant differences to each of the three probes between the two groups (sensitive vs non-sensitive) at the 0.05% level.

Lactic Acid

1) Subjects are to be seated in an upright position facing the technician.
2) Wipe the nasolabial fold and adjacent cheek area with a dry cotton pad.
3) Dip a clean cotton-tipped applicator in a container containing 10% aqueous lactic acid.
4) Briskly/gently rub the nasolabial fold/cheek area with the saturated cotton-tipped applicator for 10 seconds.
5) Set a timer for 10 minutes immediately following the application and ask the subject if she is experiencing any sensation and to describe the sensation, if any.
6) The subject will be asked each minute thereafter to grade the test site until the ten minutes has expired.
7) At the end of the 10 minutes, the test site is wiped with a cotton pad moistened with distilled water.

10% Balsam of Peru

1) Subjects are to be seated in an upright position facing the technician.
2) Wipe the cheek area adjacent to the nasolabial fold with a dry cotton pad.
3) Pipette 0.1cc of 10% Balsam of Peru probe on the test site.
4) Rub in the Balsam of Peru for ten seconds with a glass rod using a circular motion over an area the size of a dime.
5) Set a timer for 10 minutes immediately following the application and ask the subject if she is experiencing any sensation and to describe the sensation, if any.
6) The subject will be asked each minute thereafter to grade the test site until the ten minutes has expired.
7) If the subject experiences a sensation of 3 (severe), the solution is removed and the time and grade are recorded.
8) At the end of the 10 minutes, remove the Balsam of Peru using a cotton pad moistened with distilled water.

10:90 Chloroform/Methanol

1) Subjects are to be seated in an upright position with head slightly tilted back to create a level surface or subject may lay down on her back.
2) Wipe the malar eminence of the cheek area (apple of the cheek) with a dry cotton pad.
3) Make a shallow circular well, 8 mm in diameter, on the test site by gently pressing the skin with the end of a plastic cylinder previously dipped in a layer of stopcock grease. The grease forms the wall of the well.
4) Pipette 20µl of the chloroform/methanol solution into the well.
5) Immediately after filling the well with the chloroform/methanol, place a plastic disc over the well to seal. Set the timer for 5 minutes once the disc is in place.
6) Once the solution is placed in the grease ring, ask the subject if she is experiencing any sensation and to describe the sensation, if any.
7) The subject will be asked every 15 seconds thereafter to grade the test site until the five minutes has expired.
8) If at any time the subject experiences a sensation of 3 (severe), the solution is removed and the time and grade are recorded.
9) At the end of the 5 minutes or subsequent to a grade 3 sensation, remove the grease well using a dry cotton pad and wipe the area with a cotton pad moistened with distilled water.

Figure 1.

RESULTS

Of the 1017 subjects enrolled, 405 indicated they had sensitive skin; 612 did not. 1017 subjects completed the lactic acid test, 1001 subjects completed the balsam of Peru test, and 889 subjects completed the chloroform methanol test.

CLASSIFICATION OF SENSITIVITY

A breakdown of the sensitive skin subjects' responses to the questionnaire yielded the following data:

- 42% indicated that skin care products caused burning, stinging, or itching.
- 30% indicated products caused blackheads, whiteheads, or acne breakouts.
- 25% indicated that products caused rashes.
- 56% reported that dry cold winter weather exacerbated sensory symptoms.
- 14% reported irritation of facial skin due to physical stimulation.

COMPARATIVE ANALYSIS OF BUYING PATTERNS

- 80% of the sensitive skin subjects purchased products labeled for sensitive skin.

- 25% of the non-sensitive skin group purchased products appropriate for sensitive skin.

NEUROSENSORY RESPONSES

With each probe, the time to onset was statistically significantly less in the sensitive skin group; lactic acid stinging revealed the greatest difference between the two groups (see Figure 2). With each of the three probes, peak intensity was statistically significantly greater in the sensitive skin group (see Figure 3).

Time to peak response (Table I) was statistically different for the balsam of Peru (30 seconds difference) and lactic acid (90 seconds difference) probes; however, for the chloroform/methanol group the difference was less than 15 seconds on average and not statistically significantly different. The grade at onset of reaction (Table I) was higher for the sensitive skin group for each probe, but was significantly different only for the balsam of Peru and lactic acid groups.

NON-RESPONDERS

There were significant numbers of subjects who did not respond to any of the probes. Of particular interest is the number of sensitives who were non-sensitive (see Figure 4).

OTHER OBSERVATIONS

Selected demographic information noted an equal number of smokers in each group (approximately 24%). A higher percentage of the self-perceived sensitive skin group indicated having allergies (37% vs 19%) and being flushers/blushers (66% vs 40%). The self-perceived group had a slightly higher percentage of subjects with combination

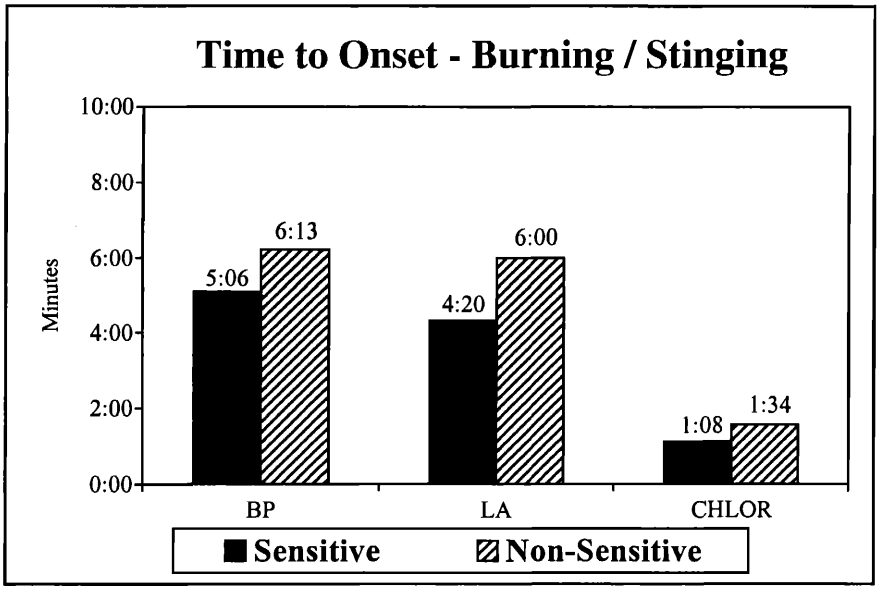

Figure 2. Time to onset of burning/stinging.

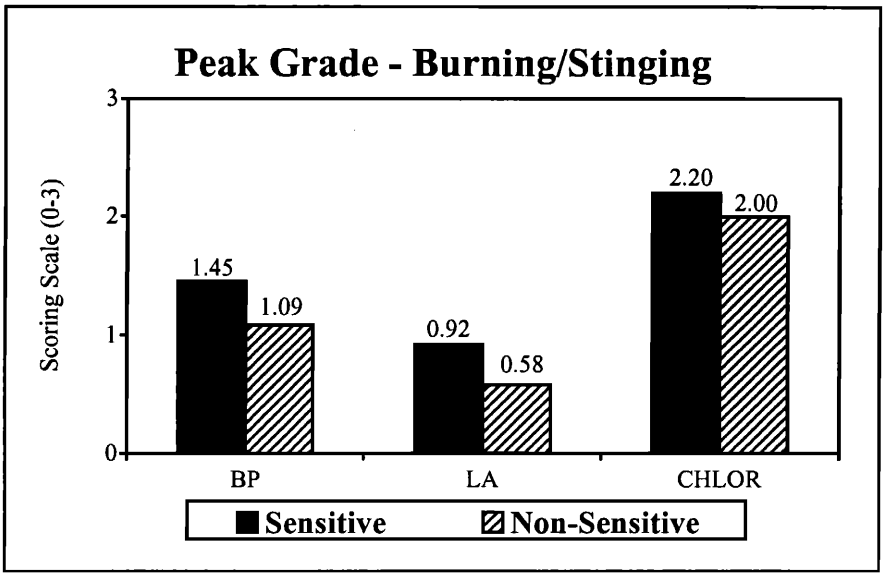

Figure 3. Peak intensity of burning/stinging.

Table I
Time to Peak Response/Grade at Onset

	Time to peak response		
	BP	LA	Chlor/meth
Sensitive skin	6:35	4:40	1:42
Non-sensitive skin	7:14	6:12	1:59
		Grade at onset	
	BP	LA	Chlor/meth
Sensitive skin	0.84	0.71	1.43
Non-sensitive skin	0.69	0.49	1.36

(oily/normal) skin, and slightly fewer had neither dry nor oily skin. Similar percentages of dry and oily skin were reported. A significantly larger percentage of the sensitive group reported that their sensitivity had increased over the years (45% vs 14%).

There were no significant differences between the responses at the five geographically diverse locations. When subjects were categorized into age groups (20s, 30s, 40s, 50s, 60s), analyses indicated that the balsam of Peru responses were significantly lower in the older age groups. Lactic acid and balsam of Peru responses were significantly higher for those who indicated they purchased products specified for sensitive skin. Subjects with skin types I and II had higher peak grades than those with skin types III and IV. Differing skin color or skin tone did not indicate a difference in response to any of the probes. Subjects who indicated that their sensitivity had changed a little or much more had higher scores for all three probes. While some of these observations showed statistically significant differences, the only one that appeared to be clinically significant was the age group response to balsam of Peru.

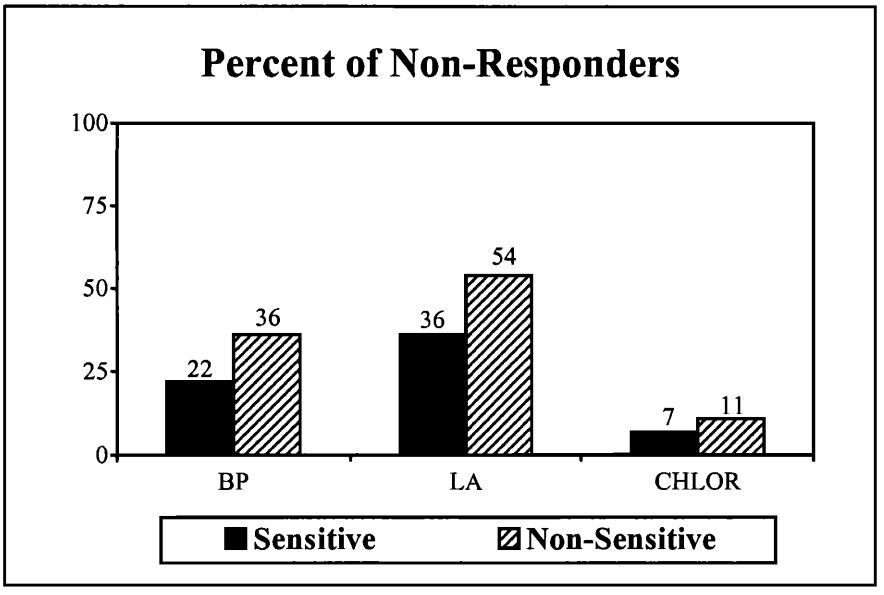

Figure 4. Percent of non-responders.

Peak responses to the chemical probes and demographic profile information were analyzed using Pearson's correlation coefficient. None of the following comparisons to peak grade indicated anything more than a trivial relationship to a subject's peak response to any of the three chemical probes: overall skin condition, skin tone, skin type, sun exposure, blushing categories, smoking status, and allergies.

SUMMARY/DISCUSSION

"Sensitive skin" is a term that has a very distinct meaning to each individual, but over a large group the definition is variable. In the literature, sensitive skin has been assessed with a facial sting test, involving a potentially strong irritant like lactic acid applied to the nasolabial fold (2). Tests conducted with materials like lactic acid, chloroform/methanol, or balsam of Peru can identify individuals with sensitive skin (3–5). The current epidemiological study was undertaken to compare individuals who classified themselves on a written questionnaire as having sensitive skin with a group of individuals self-classified as having non-sensitive skin. In this multisite study involving over 1000 participants, subjects completed a self-assessment questionnaire categorizing themselves as having sensitive or non-sensitive skin. Each subject underwent neurosensory testing with solutions of lactic acid, chloroform/methanol, and balsam of Peru. With each of the chemical probes, a statistically significant difference was found between the responsiveness of the self-assessed sensitive skin and non-sensitive skin groups for the time to onset and the peak grade achieved for each of the probes. Other parameters indicated directional differences between the self-assessed groups. The overall results indicated that the self-assessed sensitive skin group was more sensitive to the facial sting tests on average than the self-assessed non-sensitive skin group. However, the number of non-responders in the sensitive skin group and the number of strong re-

sponders in the non-sensitive skin group indicates that individual perception of sensitive skin by self-assessment may not always conform to the functional determination of sensitivity to chemical probes.

CONCLUSIONS

Our major findings were:

1. Perception of sensitive skin and reaction to probes did not correlate.
2. Questionnaire items did not forecast reactions to probes.
3. Balsam of Peru reactions decreased with age.
4. There was a surprising number of non-responders to the probes.
5. Results were not climatically dependent.

The goal of this research was to identify individuals whose acceptance of prototype formulations, under use conditions, would be predictive of that of the target consumer with sensitive skin. As we did not specifically demonstrate/define individuals with sensitive skin, it is therefore recommended to test a product designed for sensitive skin consumers utilizing a panel of subjects who both define themselves as sensitive and who react to the application of chemical probes.

REFERENCES

(1) L. P. Oddo, J. P. Bowman, L. Lockhart, and O. H. Mills, An epidemiological study of adult female sensitive skin in differing climates, *55th Annual Meeting of the American Academy of Dermatology, San Francisco, 1997,* p. 151.

(2) P. J. Frosch and A. M. Kligman, A method for appraising the stinging capacity of topically applied substance, *J. Soc. Cosmet. Chem.,* **28,** 197–209 (1977).

(3) D. Soschin and A. M. Kligman, "Adverse Subjective Responses," in *Safety and Efficacy of Topical Drugs and Cosmetics,* Albert M. Kligman and James J. Leyden, Eds. (Grune & Stratton, New York, 1982), pp. 377–388.

(4) Z. D. Draelos, Sensitive skin: Perceptions, evaluations, and treatment. *Am. J. Contact Dermatitis,* 8(2), 67–68 (1997).

(5) N. Muizzuddin, K. D. Marenus, and D. H. Maes, Factors defining sensitive skin and its treatment. *Am. J. Contact Dermatitis,* 9(3), 170–175 (1998).