

Use of Tolérance Extrême in Dermatological Practice

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Patients with hyperreactive skin on their face need products that bring relief and comfort to the skin. These cosmetic products must be adapted for sensitive skin, contain no fragrances, preservatives, or surfactants, and should be formulated using a small number of ingredients to avoid aggravating any existing contact dermatitis. The aim of the present open observational study conducted in Italy and in France was to assess the effectiveness and tolerance of a skin care program associating a cleansing lotion with a cream specifically adapted for the management of hyperreactive skin conditions.

Dermatologists regularly encounter patients who present with hyperreactive facial skin, often caused by a medical procedure or related to an underlying inflammatory dermatosis, an allergic reaction, or just sensitive skin. For these patients to feel relief, their skin's comfort level must be restored rapidly. Skin care products prescribed for patients with hyperreactive facial skin need to be suitable for sensitive skin; contain no fragrances, preservatives, or surfactants; and be formulated using a small number of ingredients to avoid aggravating any existing contact dermatitis.¹ A manufacturing process has been developed to produce skin care products that meet all of these prerequisites. Tolérance Extrême offers products that are formulated for the most demanding skin.² The

products tested in the study (cleansing lotion and cream) were used to restore the skin's comfort level, strengthen the skin barrier, and reduce skin sensitivity.

The purpose of this open observational study was to compare the use of the cleansing lotion and cream in 2 different countries to evaluate the benefits of this formulation in a variety of dermatologic situations in participants with hyperreactive skin conditions, ie, on sensitive and allergic skin, and following dermatologic procedures.

METHODS

Participants—This open observational study was conducted in France and Italy by dermatologists, allergists, and plastic surgeons. To be included, participants had to be over 18 years of age and have dermatitis (contact dermatitis, atopic dermatitis, seborrheic dermatitis, photosensitization, rosacea flare-up, intolerance to cosmetics) that did not require first-line topical corticosteroid therapy or topical immunosuppressive therapy in the week prior to consultation. Participants could not be included in the study if they were receiving systemic antihistamines, corticosteroid, or immunosuppressive treatment. If there were no signs of improvement after 7 days, local topical corticosteroids could be prescribed.

Study Design—Participants were asked to apply the cleansing lotion and cream twice a day, morning and evening, for 21 days. The main evaluation criterion was to assess the degree of overall skin irritability as evaluated

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Dr. Ayala reports he is an investigator for Pierre Fabre Dermocosmetics. Dr. Pons-Guiraud reports no conflict of interest in relation to this article. Dr. Giordano-Labadie reports she is a consultant for Pierre Fabre Dermocosmetics.

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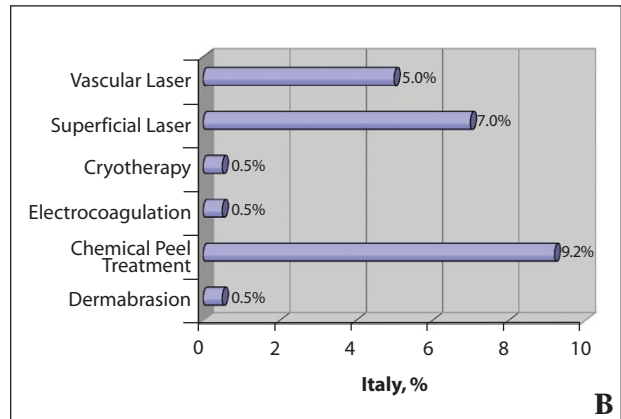
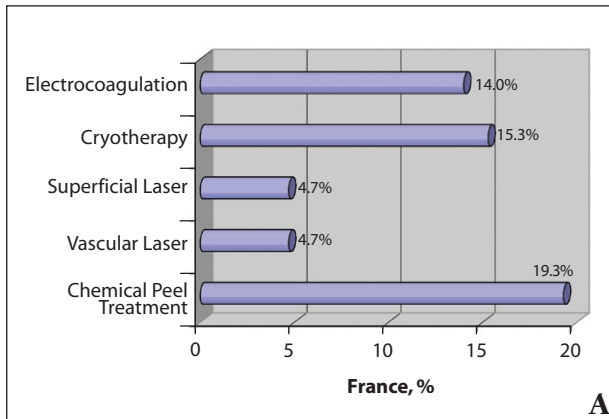


Figure 1. Postsurgical indications for the use of Tolérance Extrême skin care products in France (A) and Italy (B).

by the physician at the beginning of the study based on a 10-cm visual analog scale (VAS). Participants continued evaluations using the same method at home once a week for 3 weeks. The secondary evaluation criteria were the objective signs (erythema/redness) and the subjective signs (skin sensitivity, tightness, stinging) evaluated on a 10-cm VAS by the prescriber at baseline and by the participants on days 7, 14, and 21. The overall effectiveness of the skin care program, reflected by the improvement in the skin's comfort level, also was evaluated by participants at days 7, 14, and 21 based on a 5-point scale (none=0, slight=1, moderate=2, high=3, great=4). Treatment tolerance was evaluated by participants based on a 4-point scale (not satisfactory=0, not very satisfactory=1, satisfactory=2, very satisfactory=3) at days 7, 14, and 21. At day 21, participants evaluated cosmetic appeal based

on a 4-point scale (not at all satisfactory=0, quite satisfactory=1, satisfactory=2, very satisfactory=3). The quality and speed of reepidermization when used after an interventional procedure were evaluated by the doctor at day 21 based on a VAS and a 5-point scale, respectively (very slow=0, slow=1, quite fast=2, fast=3, very fast=4).

Statistical Analysis—The Wilcoxon signed rank test was used to compare the effectiveness criteria values at different times compared to baseline. The results were considered statistically significant ($P < .05$).

Products—The cleansing lotion and cream contain 79% and 57% concentration in soothing and anti-irritating Avène thermal spring water (ATSW) respectively, and a limited number of other ingredients.^{3,4} The cleansing lotion is composed of only 6 ingredients: ATSW, glycerin,

TABLE 1

Indications for the Use of Tolérance Extrême

Indication	Participants, % (France)	Participants, % (Italy)
Contact dermatitis	12.8	10.8
Irritant dermatitis	31	34
Intolerance to cosmetics	24	20
Atopic eczema	4	10.3
Seborrheic dermatitis	9.4	21
Rosacea outbreak	18.8	14.6
Photosensitivity	0	3.8

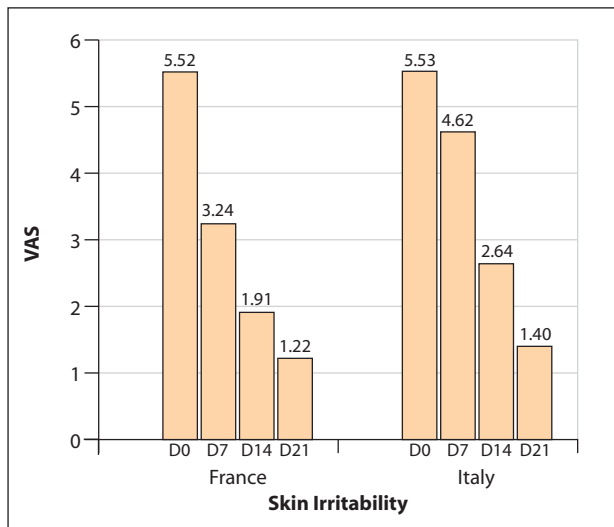


Figure 2. Progression of skin irritation at baseline and days 7, 14, and 21. A 70% improvement was observed in both France and Italy. VAS indicates visual analog scale.

paraffinum liquidum, cyclomethicone, glyceryl stearate, and sodium carbomer. The cream is composed of 9 ingredients: ATSW, glycerin, paraffinum liquidum, squalane, Carthamus tinctorius oil, cyclomethicone, glyceryl stearate, sodium carbomer, and titanium dioxide. The unique and patented manufacturing process relies on the manufacturing technology used for injectable drugs, which makes it possible to elaborate sterile pseudoemulsions. As a result, products are devoid of all irritant and allergenic potential. Thus, the 2 formulas are preservative-free, fragrance-, colorant-, and surfactant-free. This was possible because of the particular cap of the tube, the US-patented Device for Exclusive Formula Integrity cap. Thus, the use of these products permits hydration of the skin without risk of triggering irritation or an allergic reaction.

RESULTS

Of the 389 participants included in the open observational study, 335 completed it (France, n=150; Italy, n=185).

In France, 92% of participants were women and in Italy 82% of participants were women. The average participant age was 46 years in France and 42 years in Italy. Most participants in both France and Italy had combination skin that represented 78% and 60%, respectively.

In this study, the Tolérance Extrême skin care program was prescribed for interventional indications in 58% and 23% of participants in France and Italy, respectively. In both of these countries the interventional indications were mainly chemical peel treatments and superficial laser treatments (Figure 1).

The medical indications that led to the prescription of the Tolérance Extrême skin care products in this study were irritant dermatitis of the face in 31% and 34% of participants in France and Italy, respectively (Table 1).

Tolérance Extrême skin care products were prescribed as monotherapy for 88% of participants in France and 86% of participants in Italy. For the remaining participants, Tolérance Extrême cleansing lotion and cream were associated with other forms of treatment, such as, local antibiotics, antihistamines, local antiseptics, anti-inflammatories, or topical corticosteroids.

Twenty-six participants were coprescribed a local topical corticosteroid at the beginning of the study, but only 3 additional participants used a topical corticosteroid during the course of the study.

EFFECTIVENESS ON SKIN IRRITABILITY

A significant reduction in the degree of skin irritability was observed at day 7 and lasted through to the end of the study (Figure 2). At day 21, a 70% improvement was observed in both countries compared to baseline ($P < .001$).

EFFECTIVENESS ON OTHER CLINICAL SIGNS

All of the objective (erythema/redness) and subjective (skin sensitivity, tightness, stinging) clinical signs evaluated by participants significantly improved as of the first week ($P < .001$; Figure 3). At day 21, improvement

TABLE 2						
Improvement in the Skin’s Comfort Level						
Improvement Evaluation	Day 7		Day 14		Day 21	
	France, %	Italy, %	France, %	Italy, %	France, %	Italy, %
Moderate, significant, very significant	73	74	77	91	80	94

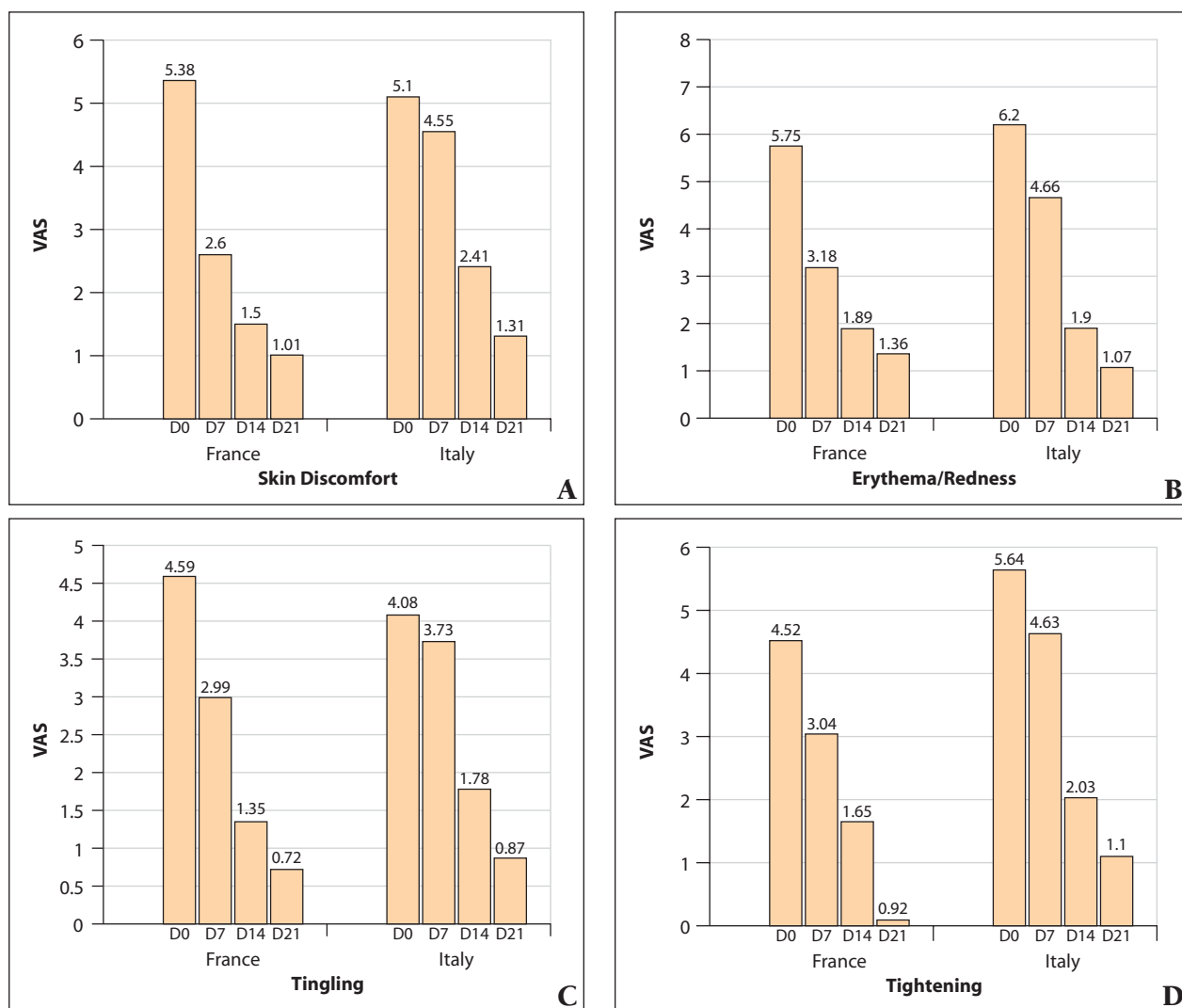


Figure 3. Evaluation of clinical signs of skin discomfort (A), erythema/redness (B), tingling (C), and skin tightening (D) at baseline and days 7, 14, and 21 in France and Italy. All clinical signs were significantly reduced between baseline and day 21 ($P < .001$). VAS indicates visual analog scale.

percentages varied between 69% and 83% based on the clinical signs evaluated.

PROGRESSION OF THE SKIN'S COMFORT LEVEL

The effectiveness of the Tolérance Extrême skin care program, evaluated in terms of the improvement in the skin's comfort level, was estimated between 73% and 74% in France and Italy, respectively, as of the first week of use of Tolérance Extrême products (Table 2).

The average time for the condition of the skin to return to a healthy, unaffected appearance in this study was 10 days in France and 12 days in Italy.

The Tolérance Extrême skin care products proved to be well tolerated in participants with hyperactive skin conditions. More than 80% of the participants answered that they were satisfied or very satisfied in

France and Italy as of the first week of application (Table 3).

COSMETIC QUALITY

The cosmetic quality of the Tolérance Extrême products (cleansing lotion and cream) were greatly appreciated. The overall cosmetic appeal quality was self-reported as being good at day 21, by 92% and 93% of participants in France and Italy, respectively.

EVALUATION OF REEPIDERMIZATION AFTER AN INTERVENTIONAL PROCEDURE

The quality of reepidermization following an interventional procedure was evaluated by the prescribers at day 21, and rated as 8.10 and 6.7 out of 10 on average according to a 10-cm VAS in France and Italy, respectively.

TABLE 3

Evaluation of Participant Satisfaction^a

Participant Evaluation	Day 7		Day 14		Day 21	
	France, %	Italy, %	France, %	Italy, %	France, %	Italy, %
TE cleansing lotion	91	83	92	94	94	94
TE cream	90	81	89	91	90	92

Abbreviation: TE, Tolérance Extrême.

^aPercentages reflect number of participants who reported they were either "satisfied" or "very satisfied" with the results of treatment.

The speed of reepidermization evaluated by prescribers was considered faster than when using the product usually prescribed for 60% and 75% of participants in France and Italy, respectively.

COMMENT

This open observational study conducted in France and Italy demonstrated that there are benefits to using the Tolérance Extrême skin care program (cleansing lotion and cream) for the treatment of sensitive and hyperreactive skin. These skin care products have been prescribed for a variety of medical and postinterventional indications. They have been shown in France and Italy to substantially reduce skin irritability and improve the clinical signs of skin hyperreactivity.² Furthermore, the cleansing lotion and cream are extremely well tolerated.

This study reports the benefits of using the skin care program in dermatological practice, both in terms of treating symptoms, such as erythema and irritation, and reepidermization. The unique manufacturing process allows for sterile and preservative-free packaging, reducing the level of skin irritation and regular use of this skin care program restores the skin's comfort level and meets the essential soothing need of hypersensitive skin while ensuring maximum safety.

These results could be attributed to the main ingredient of these products, the ATSW. Pharmacological and biological methods with sodium lauryl sulfate- or capsaicin-induced irritation have shown the soothing and anti-irritant properties of ATSW.^{5,6} These results were confirmed in many clinical studies, in which ATSW sprays were used to treat various skin conditions, such as irritation secondary to topical retinoic acid⁷; and after specific procedures, eg, aminolevulinic acid with photodynamic therapy,⁸ laser resurfacing,⁹ or fractional

photothermolysis.¹⁰ Recent data have shown that ATSW is able to induce keratinocyte differentiation,^{11,12} an effect that could be of interest in restoration of the skin barrier.

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