ORIGINAL RESEARCH Interest in Micellar Solution to Reduce Unpleasant Skin Sensations

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On behalf on the project "Ma Peau & Moi"

¹European Market Maintenance Assessment, Patients Priority Dpt, Fontenay sous-bois, France; ²NAOS, Research and Development, Lyon, France Introduction: The results from the "Objectifs Peau" project showed that approximately 30% of the French population complains of an unpleasant skin sensation at least once a day. Itching was the most frequent complaint (32%), followed by tingling (18.9%) and burning sensation (5.6%), which impact an individual's daily life. These sensations could be identified, as they were either isolated or associated with each other. The aim of this study was to evaluate the use of micellar solution to reduce these sensations, especially on sensitive skin. Methodology: A questionnaire was administered at Day 0 (D0), D2, D14, and D28 using a mobile phone application to individuals applying micellar solution (Sensibio H2O, Laboratoire Bioderma, NAOS) who spontaneously used micellar solution for sensitive skin and/or spontaneously consulted a health professional. Itching, tightness, tingling and burning sensations were evaluated by means of frequencies (never, rarely, sometimes, often or constantly) at D0, D2, D14 and D28. Responses from the questionnaire were rated (never=0, rarely=1, sometimes=2, often=3 or constantly=4) and allowed us to obtain an overall "unpleasant sensations" score, where a higher score corresponded to a higher degree of unpleasant sensations.

Results: In total, 400 evaluable individuals participated in the study (97% female, average age 38.5±13 years, 82% reported sensitive skin). The "unpleasant sensations" score improved from D2 and continued significantly on D14 and D28. The improvement rates were 47.7%, 57.9% and 62.7% at D2, D14 and D28, respectively, compared to D0. The percentages of improvement at D2, D14 and D28 were 83.2% (95% CI: 79.26; 87.21), 87.54% (95% CI: 84.01; 91.06) and 90% (95% CI: 87.06; 92.94), respectively, compared to D0.

Conclusion: The improvement in the reduction of unpleasant sensations was observed as early as 2 days after using micellar solution and increased over time. The use of this type of micellar solution, especially on sensitive skin, and the guidance of health professionals (dermatologists and pharmacists) may help to reduce the impact of unpleasant skin sensations.

Keywords: unpleasant skin sensations, micellar solution, patient centricity, itching, tightness, tingling, burning sensation

Introduction

Different terms can be found to describe sensitive skin, including "reactive", "hyperreactive", and "intolerant", which are more appropriate since skin by definition is a sensorial organ, but use of "sensitive skin" is common.¹

While unpleasant skin sensations have been widely described in the literature, the term "unpleasant sensation" was used as early as 1941 in a publication written

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by the father of investigative dermatology, Stephen Rothman² Rothman stated that an "itch is an unpleasant sensation that causes the urge to scratch"; thus began a previously mentioned journal review of the physiology of itches in 1941.³ This definition was later used to describe sensitive skin, which was defined by Misery as the appearance of unpleasant sensations such as tingling, burning, pulling, itching or pain.⁴

In everyday life, "unpleasant skin sensations" are a frequent concern; on Google alone (queried in January 2021), in English, the term "unpleasant skin sensation" generates 10 million hits; the same term in Russian [неприятные ощущения кожи] generates nearly 10 million hits; in Chinese [肌肤之感], it generates more than 44 million hits; and finally, the same term in Japanese [肌荒れ] returns more than 117 million hits.

While these unpleasant skin sensations have been described, the assessment of their prevalence is less frequent. In France, the French Dermatology Society conducted the "Objectifs Peau"⁵ project in a real population, and the first objective was to evaluate the prevalence of skin diseases. An ancillary study to the "Objectifs Peau" project looked at unpleasant skin sensations.⁶ According to this study, which included a representative sample of more than 20,000 French individuals (according to the quota method), one in three French people complained of itching at least once a day, 32.48% (95% [CI: 31.84%; 33.13%]); one in ten complained of skin pain, 10.68% (95% [CI: (10.26%; 11.11%]); almost one-fifth of respondents complained of tingling 18.9%; and 5.6% reported a burning sensation.⁶

These unpleasant sensations were more common among those who reported having dry, combination or oily skin than among those with normal skin.⁶

These unpleasant sensations are aptly named because they disrupt the daily lives of those who suffer from them, regardless of whether sensations are isolated or associated with each other.⁷ According to some authors, impairment due to unpleasant sensations is comparable to that due to pain.⁸

The main objective of this study was to evaluate in real life the frequency, evolution and impact of 4 unpleasant sensations (itching, tightness, tingling, burning sensations) in individuals using micellar solution for sensitive skin (Sensibio H2O, Laboratoire Bioderma, NAOS).

Methodology

This study was a survey performed as a real-life evaluation with no change in the daily face hygiene management of the volunteers, and this prospective study was followed up for 28 days. To allow the conditions to be as close to real life as possible, no constraint or criterion for inclusion was imposed. No ethics committee was required according to French law, and no information allowing the identification of the responders or the presence of a disease was collected. In addition, written consent from subjects was not required. Indeed, patient satisfaction surveys, experiments in human and social sciences in the field of health, evaluation of the practice of health professionals or teaching practices do not fall, in France, into the category of research covered by the Jardé law (not RPIH as defined by decree n° 2017–884 of 9 May 2017)

A questionnaire was administered at Day 0 (D0), D2, D14, and D28 via a mobile application, namely, "Ma peau et Moi" (available on Android or iOS, Figure 1, to a sample of study participants spontaneously using micellar solution for sensitive skin and/or spontaneously consulting a health professional.

Each of the 4 unpleasant sensations (itching, tightness, tingling, and burning) was assessed through their frequency (never, rarely, sometimes, often or constantly) at D0, D2, D14 and D28. Each of these responses was rated as either 0, 1, 2, 3 or 4, which allowed the possibility of creating an overall "unpleasant sensations" score and facilitated the assessment of the results.

Thus, the major criteria for the evaluation of unpleasant sensations were assessed in 3 ways and at 3 different times (D2, D14 and D28):

- The evolution of each unpleasant sensation,
- The evolution of the average global score for "unpleasant sensations",
- The prevalence of improvement in the overall unpleasantness score (ie, the percentage of respondents who described improvement between two assessments).

At 28 days, the prevalence of improvement was also evaluated according to age group, skin type, appreciation of dryness, and self-assessment of skin sensitivity (chisquare test).

Skin redness and dryness were self-assessed using a visual analogue scale (0-10).

All respondents participated in the study voluntarily and were informed of their right to refuse to answer the various questionnaires or to discontinue the follow-up without having to provide any explanation. The study

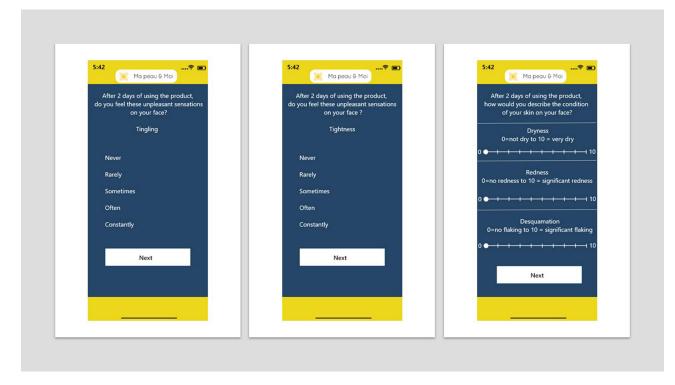


Figure I View of the application Ma Peau & Moi (Android or iOS).

participants were also informed that not answering all parts of the questionnaires would not change their relationship with their health professional.

Results

The questionnaires of a total of 400 subjects were considered complete (responses obtained at D0 and at least D28) and evaluable. Respondents who answered at D0 that they did not feel any of the 4 unpleasant sensations and that they did not show any change over time were not retained in the study.

The Population

The population is described in Table 1: 97% were women, the average age was 38.5 ± 13 years, and 82% reported having sensitive skin. Among all participants, 60.8% (n=234) reported wearing make-up daily, 90% (n=350) acknowledged that they used a facial moisturiser on a daily basis, and 70.4% (n=271) reported that the frequency of cleansing or removing make-up from the face was twice a day (morning and evening), while 25.2% (n=97) reported only in the evening.

The 4 unpleasant sensations were widely present in our sample; burning, tingling, tightness and itching were present in 92.9%, 93.2%, 94.7% and 91.5% of the respondents, respectively.

Regarding the clinical state of the skin, the dryness score evaluated on the visual analogue scale was 5.2 ± 2 44, while the redness score was 5.1 ± 3.0 .

Evolution of Each Unpleasant Sensation

Each of the unpleasant sensations improved from D2 onwards, with more than one in two respondents showing a positive change in each of the sensations (Table 2). The positive evolution of each of these unpleasant sensations was confirmed on D14 and then on D28, when nearly 3 out of 5 respondents felt a positive evolution (Table 2).

Evolution of the Average Global Score for "Unpleasant Sensations"

The "unpleasant sensations" scores were calculated. We found that in this study, the higher the score, the more unpleasant sensations were present. At each evaluation, the differential between D0 and D2 and between D14 and D28 represented the percentage rate of improvement. The score improved as early as D2 of use, and the improvement was sustained at D14 and D28. There were significant improvements at all time points (Table 3). The rates of improvement at D2, D14, and D28 compared to D0 were 47.7%, 57.9% and 62.7%, respectively.

		N (%)	
Туре	Male	13 (3.3%)	
	Female	387 (96.8%)	
Age group	Under 20 years old	19 (4.8%)	
	From 20 to 39 years old	180 (45.6%)	
	From 40 to 59 years old	176 (44.6%)	
	Over 60 years old	20 (5.1%)	
Average age	Average (SD)	38.5 (12.96)	
	Median (Range)	40.0 (8.0–75.0)	
	Q1–Q3	[31.0, 48.0]	
Skin type	Oily	20 (5.2%)	
	Mixed	186 (48.4%)	
	Normal	44 (11.5%)	
	Dry	104 (27.1%)	
	Very dry	30 (7.8%)	
Skin sensitivity	Not sensitive	9 (2.3%)	
	Not very sensitive	58 (15.1%)	
	Sensitive	202 (52.5%)	
	Very sensitive	116 (30.1%)	

Table I Population Characteristics

Abbreviation: SD, standard deviation.

Prevalence of Improvement in the Overall Unpleasantness Score

The percentage improvement at D2, D14 and D28 compared to D0 was 83.2% [CI: 79.26; 87.21], 87.54% [CI: 84.01; 91.06] and 90% [CI: 87.06; 92.94], respectively (Table 3). However, no significant difference was observed at D28 for the prevalence of improvement in subpopulations according to age, skin type, appreciation of dryness, and self-assessment of skin sensitivity (data not shown). No prevalence was less than 75%.

A total of 83.6% of participants stated that after using the product for 28 days, they observed a reduction in their skin sensitivity.

Assessment of Dryness and Redness

On D2, two out of three participants reported improvement in the dryness (65% [CI: 59.71;70.28]) and redness (64.9% [CI: 59.41;70.38]) of their skin (Table 4). At D28, at least **Dove**press

74.0% reported an improvement in both dryness and redness (Table 4).

Discussion

This study showed a positive evolution of each unpleasant sensation (burning, tingling, tightness and itching) and of the average global score for "unpleasant sensations" over 28 days, as well as the prevalence of improvement in the overall unpleasantness score. These improvements as early as D2 showed the rapidity of action, and its amplification on D28 demonstrated the sustainability of the effect. According to our results, it appears that daily skin hygiene using micellar solution helps to reduce unpleasant skin sensations.

In view of these factual results, we can speculate how micellar solution reduces unpleasant sensations. This micellar solution is a no-rinse cleansing product with a physiological pH (between 4.5 and 5.5), which is formulated with highly purified water and a non-ionic surfactant that effectively removes make-up, pollutants and pollen.⁹ As airborne pollutants have an impact on skin health, probably by inducing inflammation and oxidative stress,¹⁰ and can impair skin barrier function, as described for pollen,¹¹ they can exacerbate skin sensitivity. Thus, by preventing their penetration, the micellar solution can help to maintain the integrity of the skin barrier, limiting unpleasant skin sensations. In addition, the formula contains a patented association of active ingredients that contribute to the reduction of unpleasant skin sensations: rhamnose reduces inflammation.¹¹ mannitol limits the amount of free radicals,¹² and xylitol has moisturizing properties.¹³ In addition, a cucumber extract provides a moisturizing effect. As cosmetic products have recently been identified as the main trigger of the exacerbation of sensitive skin,¹⁴ skin care products need to be very well tolerated to respect and to preserve the natural balance of the skin. Therefore, the careful selection of ingredients is very important and includes criteria such as their number (limited ingredients), concentration (in line with efficacy and toxicology requirements) and purity (reduced level of potentially harmful trace elements such as heavy metals). In this context, the micellar solution used in this evaluation was developed according to these principles and in line with the ecobiological approach. Ecobiology is an original approach that considers the skin as a constantly evolving ecosystem that interacts with its environment and whose natural resources and mechanisms must

Evolution Between	Burn Se	ensation	Tingling		Tightness		Itching	
D0 and D2	Ν	%	N	%	N	%	N	%
Total N	320		307		307		317	
Positive evolution	179	55.94%	196	63.84%	237	77.20%	190	59.94%
D0 and D14								
Total N	320		318		326		316	
Positive change	195	60.94%	214	67.30%	256	76.00%	208	65.82%
D0 and D28								
Total N	400		400		400		400	
Positive change	243	60.75%	270	67.50%	318	79.50%	242	60.50%

Table 2 Evolution of Unpleasant Sensations at D2, D14 and D28

be preserved.^{15,16} The results of this evaluation suggest that the micellar solution is especially suitable for sensitive skin and thus confirm the relevance of this approach.¹⁷

 Table 3 Evolution of the Rate of Improvement and of the

 Prevalence of Improvement in the Overall Unpleasantness Score

Comparison Day 0–Day 2 (N=340)				
	Day 0	Day 2		
Mean [SD]	5.99 [2.89]	3.14 [2.97]***		
Rate of improvement		47.66%		
Prevalence of improvement		83.2% [IC: 79.26; 87.21]		
Comparison Day 0-Day 14 (N=337)				
	Day 0	Day 14		
Mean [SD]	6.00 [2.88]	2.53 [2.47]***		
Rate of improvement		57.88%		
Prevalence of improvement		87.54% [IC: 84.01; 91.06]		
Comparison Day 0–Day 28 (N=400)				
	Day 0	Day 28		
Mean [SD]	6.14 [2.91]	2.29 [2.40]***		
Rate of improvement		62.68%		
Prevalence of improvement		90% [IC: 87.06; 92.94]		

Note: ***p<0.001.

Abbreviation: SD, standard deviation.

Although this study was a survey, and enrolment favoured women to men, the results show the importance of the skin cleanser. The use of this type of micellar solution, especially on sensitive skin, and the guidance of health professionals (dermatologists and pharmacists) may help to reduce the impact of unpleasant skin sensations and thus the associated daily life impairment.

A study published almost 20 years ago noted that several products recommended for sensitive skin could have an irritating effect due to their pH.¹⁸ Therefore, it is particularly important for sensitive skin to choose the right cleansing products. However, individuals are not always aware of the potential irritation of cleansing skin care. Health professionals have an informative and advisory role towards their patients to help them choose adapted products. Taking care of our skin means taking care of it from the moment we clean it. Education through simple gestures to ensure optimal skin hygiene could be relayed by health professionals and patient associations, even from a very young age in schools, for example, in the same way as brushing one's teeth.

Conclusion

Unpleasant skin sensations disturb the daily life of those who suffer from them. Our study shows that suitable

Table 4	Evolution	of Dry	ness and	Redness	at D0 and I	D28
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Average VAS	Dryness	Redness	
Day 0	5.2 ± 2.44	5.1± 3.01	
Day 28	2.9 ± 2.87	2.8 ± 2.90	
p-value	<0.001	<0.001	

skin hygiene, such as the use of micellar solution designed for sensitive skin, allows us to reduce the intensity of these sensations in relevant clinical proportions regardless of the age group or the skin type. Health professionals have a key role in educating and informing patients about the importance of hygiene, especially for sensitive skin.

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Disclosure

GF, SM are employees of NAOS, DD reports being an employee of NAOS, Bioderma. The authors report no other conflicts of interest in this work.

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