

Topical effectiveness of a cosmetic skincare treatment for acne-prone skin: A clinical study

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K E Y W O R D S

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A B S T R A C T

Background Physiological acne is a milder form of clinical acne and is very frequent in adult women (18 years of age and older). Acne therapy is usually unnecessary in such cases, and so appropriate cosmetic treatments are sought.

Objectives To determine the effectiveness of a topical cosmetic hydrating skincare treatment for adult acne-prone skin (Normaderm, Vichy, France) against the clinical signs of physiological acne: few inflammatory and retentional lesions, uneven (grainy) skin relief, dilated pores, and occasional and/or local hyperseborrhea.

Methods Within the study, the tested product's keratolytic, antimicrobial, and antiseborrheic properties, and its overall ability to improve the clinical signs of physiological acne present in adult subjects were evaluated through objective and clinical evaluation methods by the investigators and through self-evaluation questionnaires by the subjects themselves. The study group was composed of 50 adult women between 18 and 35 years of age with combination or oily acne-prone skin, who were chosen according to previously defined inclusion criteria. They applied the product tested twice daily on thoroughly cleansed skin for a period of 2 months. The results were evaluated after 30 (± 2) and 60 (± 2) days.

Results The number of inflammatory and retentional lesions on the forehead, cheeks, and chin decreased after 60 days of use (an average of 30.7% and 70.7%, respectively). The level of sebum secretion on the forehead decreased by 33.4% and the level of skin scaling decreased by 38.5% after 60 days of use. The moisture content in the horny layer on the forehead, cheeks, and chin increased by an average 39.7%. The decrease in pore size and content after 60 days of use was very noticeable. The subjects evaluated all the studied characteristics of the product tested very positively, with results already showing after 30 days of use.

Conclusions The results of the study confirm that the product tested is suitable for the cosmetic care of adult acne-prone skin, either as an independent cosmetic hydrating skincare treatment, as a complementary cosmetic part of acne therapy, or as a subsequent cosmetic regimen to sustain the results of the acne therapy for a longer period of time.

Introduction

Acne is well understood to result from the interplay of three factors: (1) hyperkeratinization and obstruction of sebaceous follicles caused by abnormal desquamation of the infundibular epithelium, (2) androgen-stimulated increase in sebum production, and (3) colonization of the follicle by *Propionibacterium acnes*, which generates inflammation (1, 2). This multifactorial skin disease can be divided according to the type and severity of the clinical lesions (comedones, papules, pustules, nodules, and cysts), but can be also classified according to the age of onset (infantile, adolescent, and adult acne). The typical clinical picture of acne is an eruption located on the face, with the upper trunk being affected as well (3). The dermatological treatment of acne vulgaris has been discussed by many authors (4–9). The most common treatments include the topical use of comedolytics and antimicrobial agents and the topical and/or systemic use of antibiotics, retinoids, and oral contraceptives (3).

In westernized societies, facial acne is a very common skin disease afflicting 79 to 95% of the adolescent population and 54% of women 25 years of age or older (10). The form of facial acne in adult patients is usually milder than that in adolescent patients. In most cases, it is the skin's response to stress (11), diet (12), and hormonal fluctuations (13).

Poli et al. (14) conducted an epidemiological study of acne on a population of 4,000 adult women 25 to 40 years of age in France using a questionnaire about their skin type, lifestyle factors influencing acne, and quality of life. The results of 3,305 useable questionnaires showed a prevalence of clinical acne in 17% of the population and a prevalence of "physiological" acne in 24% of the population. Clinical signs present in patients with physiological acne, as a milder form of clinical acne, are very few pustules and/or papules on the face, retentional lesions such as microcysts, open and closed comedones (blackheads, whiteheads) that cause an uneven (grainy) skin relief, dilated pores, and occasional and/or constant hyperseborrhea resulting in localized shine, especially on the T-zone (15). These imperfections are more often localized in the lower section of the face, on the chin and mandibular areas, and occasionally also on the forehead. Women most often express their problem using terms such as "unclear complexion" or "problem skin" rather than the term "acne," most probably because they associate acne with adolescence. Dermatological treatment in such cases is often unnecessary, and so appropriate cosmetic treatments are sought.

Cosmetic products for treating acne-prone skin should be formulated to act on all three factors involved in the formation of acne: (1) keratolytic active

ingredients such as salicylic and glycolic acid, which promote microexfoliation to unclog blocked sebaceous follicles and prevent their repeated obstruction; (2) antiseborrheic active ingredients, which regulate sebum production and secretion; and (3) antimicrobial and anti-inflammatory active ingredients (e.g., copper and zinc pyrrolidone carboxylates), which limit the proliferation of *P. acnes*. Active ingredients that regulate the renewal of the epidermis are also greatly favored in such products.

For the purpose of this study, a cosmetic hydrating skincare treatment for adult acne-prone skin was clinically tested on a group of women between 18 and 35 years of age. The primary objective of the study was to evaluate the effectiveness of the hydrating skincare treatment for adult acne-prone skin: its keratolytic, antimicrobial, and antiseborrheic properties, and its overall ability to improve the clinical signs of physiological acne present in adult subjects. Another objective of this study was to evaluate the effectiveness of the product and its cosmetic properties by the subjects themselves through self-evaluation questionnaires.

Materials, methods, and subjects

The topical cosmetic hydrating skincare treatment for adult acne-prone skin (Normaderm) and the neutral cleansing solution (Normaderm micellar solution) were provided by Vichy, France. Both products are non-comedogenic and hypoallergenic, formulated especially for sensitive skin.

Micellar solution is a neutral water-based cleansing solution formulated with micellar technology. It contains non-ionic surfactants that cluster into micelles in water at the critical micellar concentration and act as "micro-captors." It also contains a rose extract (*Rosa galica*) that has been proven to have an antagonistic activity on the neuromediator receptors generated by the nerve fibers in the epidermis (substance P) (15). The water-based cleanser does not contain any antimicrobial or anti-acne active ingredients. It was used twice daily on the entire facial area to thoroughly cleanse the skin before applying the product tested.

The Normaderm anti-imperfection hydrating skincare treatment for oily and acne-prone skin is an oil-in-water emulsion based on microfiber technology (patent pending). The principle active ingredients are: (a) glycolic and salicylic acid, which have keratolytic properties, (b) copper and zinc pyrrolidone carboxylates, which have bactericidal, fungicidal, anti-acne, and antiseborrheic properties, and (c) an extract of green algae (*Chlamydomonas reinhardtii*) that acts as a cellular stimulant (proven in vitro on a keratinocyte culture) (15). The product tested also contains a pore-tightening witch hazel extract and glycerin, which is

well known as a humectant (16).

Sebum-measuring patches (Sebutape[®]) and adhesive skin surface sampling discs (Corneodiscs by D-Squame[®]) were purchased from CuDerm Corporation, Texas, USA. The Monaview Camera and the Skin Diagnostic SD27 are produced by Courage + Khazaka Electronic GmbH, Germany, and were purchased from Monaderm, Monaco.

The study was conducted on two groups of women 18 to 35 years of age, one in Ljubljana and one in Zagreb, and included 50 subjects altogether. The subjects were selected according to the following inclusion criteria: (a) combination or oily acne-prone skin with 0 to 5 inflammatory lesions and/or up to 20 retentional lesions present on all three 2 × 2 cm areas of the central forehead, cheek (randomly chosen), and chin, (b) phototypes II–IV, and (c) Sebutape score on the forehead ≥ 2. The subjects signed an informed consent to participate in the study and accepted the following conditions: (a) perform a wash-out of usual cosmetic

products 3 days before the beginning of the study, (b) no application of any cosmetic products or makeup before visiting the investigator, (c) in the case of an ongoing contraceptive regimen, this must have been going on for at least 3 months and no changes in the regimen were allowed during the period of the study, and (d) no facial treatments of any kind at beauty institutions (e.g., deep cleansing treatments, peelings, cleansing masks, artificial tanning, etc.) during the study period. At each visit, the investigator checked whether the subject was properly following the study protocol.

The subjects applied the product tested twice daily, morning and evening. The duration of the study was 60 days. The effectiveness of the product tested was evaluated after 30 (± 2) and 60 (± 2) days of use by the investigators (see Table 1) and by the subjects themselves through a self-evaluation questionnaire, which contained nine yes/no questions.

Table 1. Characteristics of the product evaluated and the evaluation methods used.

Characteristics	Evaluation method
Overall effectiveness against physiological acne	Clinical exams on day D0 to verify the inclusion and exclusion criteria of the subjects in the study groups, to evaluate the initial skin condition, and to count the inflammatory and retentional lesions on 2 × 2 cm areas of the central forehead, cheek, and chin; at day D30 and D60 to evaluate the overall improvement of skin condition and to check for manifestations of possible intolerance reactions to the product tested. The clinical evolution of the skin condition was documented by standardized photography prior to and during the entire period of the study. Self-evaluation questionnaires at D30 and D60.
Antimicrobial effectiveness	Count of inflammatory lesions (papules, pustules) and retentional lesions (opened/closed comedones) on 2 × 2 cm areas of the forehead, cheek, and chin at D30 and D60. Self-evaluation questionnaires at D30 and D60.
Antiseborrheic effectiveness	Sebum secretion determination with Sebutape on the forehead at D0, D30, and D60. The Sebutape was placed on the forehead, previously swabbed with an ethanol:water mixture of 70:30 (v/v) for 20 minutes. The microporous film acted as a passive collector of the sebum and the Sebutape score was subsequently assigned by comparing the Sebutape sample with the producer's standard scale of sebum secretion (1–5; 5 being the highest sebum-secretion score). Self-evaluation questionnaires at D30 and D60.
Keratolytic effectiveness	Sampling of the skin surface with Corneodiscs on the cheek (randomly chosen site) at D0, D30, and D60. The transparent adhesive discs adhered to corneocytes of the superficial stratum corneum. The Corneodisc score was assigned by comparing the Corneodisc sample with the producer's standard scale of skin scaling (1–5; 5 being the highest scaling score). Self-evaluation questionnaires at D30 and D60.
Astringent effectiveness	Examination of the central forehead, cheek, and central chin zones with the Monaview camera (areas of 2 × 2 cm; 30× enlargement of the skin surface using polarized and nonpolarized lighting) at D0, D30, and D60.
Hydrating capacity	Measuring moisture content in the horny layer with the Skin Diagnostic SD27 (the Corneometer [®]). This measurement is based on the capacitive method. The dry stratum corneum is a dielectric medium and its dielectric properties change with the moisture content. The measuring capacitor shows changes in capacitance according to the moisture content of the samples.
Cosmetic characteristics	Self-evaluation questionnaires at D30 and D60.

Results and discussion

The 50 subjects were young women (mean age \pm SD: 23 ± 5.24 years) with a mild or moderate form of physiological acne and combination or oily skin. The imperfections were mainly concentrated on the mandibular area, with the cheeks and forehead being affected to a lesser extent. The subjects followed the study protocol correctly and none of them demonstrated any intolerance manifestations towards the product tested.

The results of the clinical exam (counting the inflammatory and retentional lesions), sebum excretion and keratolytic action determinations, and the measurement of the moisture content in the horny layer

are presented in Table 2. All the objective evaluation methods used to determine the effectiveness of the product tested gave very positive results. The number of retentional lesions on all three areas of the face examined (forehead, cheeks, and chin) decreased significantly after 60 days of use, proving the overall effectiveness of the product tested against physiological acne. The reduction of the Sebutape score by 33.4% after 60 days of use proved the antiseborrheic effectiveness, and the reduction of the Corneodisc score by 38.5% proved the keratolytic effectiveness of the product tested. The increase in the horny layer moisture content after 30 and 60 days of use additionally confirms its favorable hydrating properties.

Table 2. Results of the objective evaluation methods used to determine the effectiveness of the hydrating skincare treatment tested for acne-prone skin ($\alpha = 0.05$).

Objective evaluations	D0	D30	D60	(D0 – D60) / D0 \times 100%
Number of inflammatory lesions (papules, pustules) ($n = 30$)				
Forehead	0.29 ± 0.27	0.17 ± 0.15	0.17 ± 0.15	41.4%
Cheek	0.67 ± 0.29	1.00 ± 0.45	0.50 ± 0.20	25.4%
Chin	0.67 ± 0.58	0.67 ± 0.29	0.50 ± 0.30	25.4%
Number of retentional lesions (open and closed comedones) ($n = 30$)				
Forehead	6.67 ± 1.10	4.17 ± 0.53	2.17 ± 0.27	67.5%
Cheek	5.83 ± 1.49	3.33 ± 0.49	1.67 ± 0.37	71.4%
Chin	7.50 ± 1.23	4.50 ± 0.87	2.00 ± 0.45	73.3%
Sebutape score on the forehead ($n = 50$)				
	3.50 ± 0.35	3.50 ± 0.19	2.33 ± 0.42	33.4%
Corneodisc score on the cheek ($n = 50$)				
	3.25 ± 0.14	2.33 ± 0.16	2.00 ± 0.27	38.5%
Moisture content in the horny layer ($n = 50$)				(D60 – D0) / D60 \times 100%
Forehead	27.29 ± 4.15	44.33 ± 3.35	42.20 ± 3.71	35.3%
Cheek	32.86 ± 5.18	37.50 ± 3.41	51.80 ± 4.29	36.6%
Chin	39.14 ± 4.39	50.17 ± 3.00	48.00 ± 3.77	47.2%

The clinical examination of the entire facial area in most cases showed an improvement in the clinical picture of the skin. A few subjects experienced an outburst of inflammatory lesions after the first month, but a significant improvement followed after the second month of product use. This could be attributed to

the product's keratolytic or "pore-unclogging" action. The decrease in pore size and content after 60 days of product application was also very noticeable by examining the skin's surface with the Monaview camera, thus demonstrating the astringent effectiveness of the product tested (Table 3).

Table 3: Pictures of the skin surface on the central forehead, cheek, and chin (30×) using a Monaview camera and polarized lighting.










Area, Subject	D0	D30	D60
Forehead, Subject 4			
Cheek, Subject 18			
Chin, Subject 3			

Table 4: Results of the self-evaluation questionnaires.

Subjective evaluations (<i>n</i> = 50)	D30	D60	Characteristic evaluated
Clearer skin	85%	81%	Epidermal renewal
Tighter pores	71%	79%	Astringent effectiveness
Less inflammatory lesions	73%	75%	Antimicrobial effectiveness
Less oily (shiny) skin	60%	75%	Antiseborrheic effectiveness
Less clogged pores	81%	81%	Keratolytic effectiveness
Smoother skin	90%	81%	Keratolytic effectiveness
Improved appearance of the skin	79%	79%	Overall effectiveness
Good makeup base	79%	79%	Cosmetic characteristics
Very good or good cosmetic characteristics	97%	91%	Cosmetic characteristics

The effectiveness of the hydrating skincare treatment tested for acne-prone skin was also evaluated by the subjects (Table 4). All of the studied characteristics of the product were evaluated very positively, with visible results already after 30 days of use. In addition, the cosmetic characteristics of the product tested (quality of cosmetic base for daily makeup, texture, pleasure of use) were evaluated as good or very good by over 90% of the subjects. Renzi et al. (17) established that improving the physician's interpersonal skills could increase patient satisfaction, which is likely to have a positive effect on treatment adherence and health outcomes. We believe that the same can be supposed for patient satisfaction concerning complementary cosmetic treatments in dermatology. Pleasant textures and cosmetic qualities of such products may promote a regular daily routine of product use and thus a faster visible improvement of skin condition, especially in the case of long-term skin conditions such as acne.

Studies to date have shown that acne affects the general quality of life of patients, including their self-image, self-esteem, and emotions (18–23). In severe cases, the quality of life impairment is even comparable with general medical conditions such as chronic disabling asthma, epilepsy, diabetes, back pain, or arthritis (24). These findings are explained by the fact that acne mostly involves the face and by the long-lasting nature of this skin condition. Lasek and Chren (21) ascertained that the most bothersome factor for their group of acne vulgaris patients was the appearance of the skin. Appearance was most troublesome for older patients in their late 20s and 30s, who have long since moved beyond the adolescent period. Improving the appearance of the skin is crucial in improving the quality of life of adult acne patients. Therefore, cosmetics such as skincare treatments and

camouflage cosmetics should have an important role in acne and post-acne treatment.

The question to what extent dermatologists should become involved in cosmetics and cosmetology is very important with regard to the future development of dermatology, and this task should be performed on sound scientific grounds (25, 26). Such studies may therefore set the foundations for “evidence-based cosmetic dermatology.”

Conclusions

Within this study, a new topical cosmetic hydrating skincare treatment for adult acne-prone skin (Normaderm, Vichy) was clinically tested on a group of 50 women between 18 and 35 years of age. The results of the objective and clinical evaluations performed by the investigators and those acquired through a self-evaluation questionnaire answered by the subjects confirmed the keratolytic, antimicrobial, antiseborrheic, and astringent properties of the product tested, and its overall ability to improve all the clinical signs of physiological acne present in adult subjects. The results of the study also confirmed the hydrating action of the product tested, which makes it suitable for the cosmetic care of adult acne-prone skin, either as an independent cosmetic hydrating skincare treatment, as a complementary cosmetic part of the acne therapy, or as a subsequent cosmetic regimen to sustain the results of the acne therapy for a longer period of time. It may also be concluded that the agreeable cosmetic characteristics of the product tested and patient satisfaction can encourage its regular daily use.

It has already been demonstrated that decorative (camouflage) cosmetics improve the quality of life of patients with disfiguring skin diseases (26, 27), including acne, but there are no studies to date that report

the influence of cosmetic skincare treatments for acne-prone skin on the quality of life of adult acne patients. Therefore, the investigation of the effect of the improvement of the skin's condition and appearance

generated by such products would be a very interesting and reasonable direction to proceed in with our research.

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