

Effectiveness of EFFACLAR H ISO-BIOME preparations as an adjunct to conventional treatment of acne vulgaris — results of an observational study

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ABSTRACT

Background: Although topical dermocosmetics are widely used care products, only a few studies investigated their effectiveness in enhancing the tolerance and efficacy of medical anti-acne therapies. The primary objective of this study was to assess the safety and efficacy of EFFACLAR H ISO-BIOME cream and washing cream as an adjunct to pharmacological treatment (local and/or systemic) administered for at least 12 weeks in patients with mild to very severe acne vulgaris.

Material and methods: This observational study was conducted in patients (n = 306) aged 14 years and over with mild to very severe [Global Acne Severity Scale (GEA) 1–5] acne vulgaris. Participants were instructed to apply the EFFACLAR H ISO-BIOME cream and washing cream twice daily for at least 12 weeks along with prescribed anti-acne therapy (topical agents, oral isotretinoin, or systemic antibiotics/spironolactone combined with topical agents).

Results: The treatment regimen led to an improvement in GEA scores in 88.9% of all patients (p < 0.05). Statistically significant changes were observed in the reduction of sebum secretion, number of papules and pustules, postinflammatory hyperpigmentation, and erythema (p < 0.05). The vast majority of dermatologists and patients rated the tolerance of the products as very good (97% and 94%, respectively). The quality of life of most patients improved by the end of the study.

Conclusions: EFFACLAR H ISO-BIOME cream and washing cream are safe and effective products used as adjunctive treatment to topical or systemic therapy of mild to very severe acne vulgaris.

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Keywords: dermocosmetics, EFFACLAR H ISO-BIOME, acne

INTRODUCTION

Acne vulgaris is a chronic inflammatory skin disease that affects the pilosebaceous units of the skin. The typical distribution of acne lesions involves the face, back, and chest, particularly abundant with active sebaceous glands. The clinical picture is diverse and embraces mild comedonal acne to its severe fulminant variant [1]. Although acne is most common in adolescents, it may also occur in children and adults [2]. The pathogenesis is multifactorial and encompasses a complex interplay of excessive sebum

production, alteration in the keratinization process, follicular colonization of *Cutibacterium acnes*, and inflammation [3]. Moreover, factors like hormones, genetics, microbiota, innate and acquired immunity, and the environment may contribute to the onset of acne [4]. A modern approach to acne treatment should target as many pathogenetic factors as possible. Current international guidelines for managing acne focus on topical and systemic therapies depending on the severity of acne [1]. Along with a well-selected treatment modality, a critical approach is proper skin care. Nowadays,

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many dermocosmetic products with various active ingredients dedicated to acne skin are available and have been used in monotherapy, combined therapy, and maintaining therapy of acne. Nevertheless, the vast range of products does not have clinical studies supporting their efficacy. This is the first observational study to assess the effectiveness and tolerance of dermocosmetics — EFFACLAR H ISO-BIOME cream and EFFACLAR H ISO-BIOME washing cream along with conventional anti-acne drugs in patients with mild to severe acne vulgaris.

MATERIAL AND METHODS

The design of the study

This study was designed by experts from La Roche-Posay. The primary objective of this study was to assess the safety and efficacy of EFFACLAR H ISO-BIOME cream and washing cream as an adjunct to pharmacological treatment administered for at least 12 weeks to individuals with acne vulgaris. Subjects provided written informed consent before enrolment, which was approved by the ethics committee. Patients had to fulfil the following inclusion criteria to be eligible for participation in the study: diagnosed with mild to very severe acne vulgaris according to the criteria of the Global Acne Severity Scale (GEA) and one of concomitant treatment — topical agents (i.e., benzol peroxide, adapalene, trifarotene, azelaic acid, tretinoin, clindamycin, or combined topical agents); oral isotretinoin; combined treatment with oral agents (antibiotics or spironolactone) and topical treatment. Only individuals 14 years and older were enrolled. Females who were pregnant or breastfeeding could not enter the study. All patients were recommended to use EFFACLAR H ISO-BIOME washing cream and topical EFFACLAR H ISO-BIOME cream twice daily (day and night). Subject participation involves two clinic visits: initial and evaluation ones. Acne severity was stratified by physicians according to the GEA score at both visits. Next, a questionnaire prepared for this study was completed by each participant according to the schedule of visits. Additionally, at the evaluation visit, subjects were queried regarding compliance and adverse events.

Acne grading system and research tools

The acne severity was assessed in all the patients according to the GEA, which allocated patients a grade from 0 to 5 (0 — clear, no lesions; 1 — almost clear, almost no lesions; 2 — mild; 3 — moderate; 4 — severe; 5 — very severe) [5]. Physicians independently evaluated patients on each visit. The research tool that allowed to standardize the data collected was the questionnaire. The first part of the questionnaire included demographic data (gender, age), information about acne (lifetime prevalence of acne, subtype of acne, location, complications of acne (post-inflammatory

hyperpigmentation, redness, and scarring) severity of sebum secretion, assessment of skin sensitivity), use of contraception, current acne treatment, and use of sunscreens. The second part was focused on the patient's subjective assessment — life quality index, evaluation of skin sensitivity — the presence of pruritus, pain, stinging, or tingling. The investigator and patient also performed local tolerability assessments and satisfaction surveys at the evaluation visit.

Statistical methods

To verify the significance of the obtained results, a non-parametric test was performed for two dependent samples (Wilcoxon signed-rank test). P-values less than 0.05 were considered significant.

RESULTS

Study population

A total of 306 participants with acne vulgaris diagnosed according to the typical clinical manifestation were enrolled for this observational study. Out of all studied subjects, 60.8% were women (n = 186) and 39.2% were men (n = 120). Most of the investigated group were Caucasians (80.7%) aged up to 21 years (60.8%) with Fitzpatrick skin phototype II (67.6%) (Fig. 1). There was a predominance of patients in which acne occurred 1–2 and 2–5 years before the initial visit (26.1% and 24.8%, respectively). In 43.8% of all cases, the disease severity was evaluated as moderate (GEA 3). Most subjects had a papulopustular subtype of acne (67%). The majority had lesions in the so-called U-zone — both cheeks (68%) and T-zone — forehead, nose, and chin (61%). Of patients, 43.5% used EFFACLAR H ISO-BIOME preparations (cream and washing cream) as adjunctive therapy to monotherapy with topical treatment, 20.9% to topical and systemic treatment, and 35.6% to oral isotretinoin (Fig. 2). Every third of surveyed women used contraception, mainly combined oestrogen-progestin oral contraceptives (51.6%).

Efficacy

Over the course of 12 weeks of treatment, a significant difference in GEA score was observed in 88.9% of patients — of which 33% had improvement of two or more grades on the GEA score ($p < 0.05$) (Fig. 3). The statistically significant changes were also observed in sebum secretion, number of papules and pustules, postinflammatory hyperpigmentation, and erythema ($p < 0.05$). The overall percentage change in skin sensitivity measured at the evaluation visit was a 60.3% improvement in erythema, 58.7% in scaling, and 64.5% in dryness ($p < 0.05$). This improvement was also observed in patients' surveys as counted by the proportion of subjects attaining reduction in pruritus (57.4%), tingling (30.6%), and stinging (55.6%) (Fig. 4). Interestingly, all patients, who experienced moderate to severe pruritus

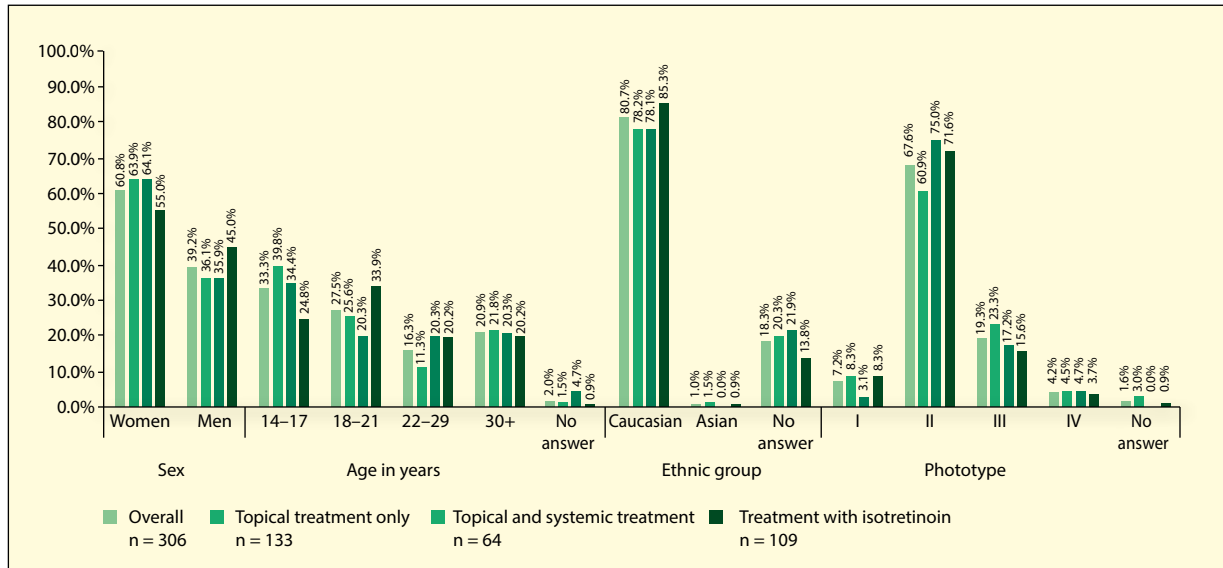


Figure 1. Demographic and clinical characteristics of the study group

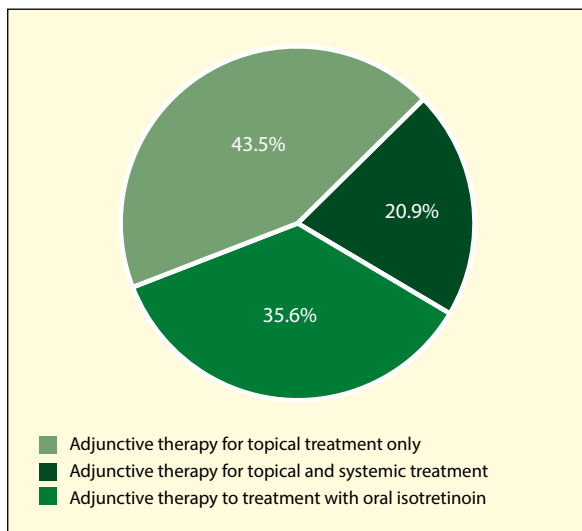


Figure 2. Methods of treatment in the analysed groups of patients

or tingling, reported alleviation of these symptoms, and 95% of those with at least a moderate burning sensation experienced a reduction. Notably, in the severe cohort of patients receiving isotretinoin, there was a complete reduction in the most intense erythema, scaling, and dryness, as well as itching, tingling, and stinging sensations. EFFACLAR H ISO-BIOME cream and washing cream demonstrated excellent tolerability based on both investigator-rated and subject-rated local tolerability assessments. There was no need for modifying the treatment regimen in patients using cream and washing cream in 97.4% and 96.4% of subjects, respectively.

Quality of life

According to the collective analysis of all patients, acne lesions significantly impaired quality of life. 58% of patients

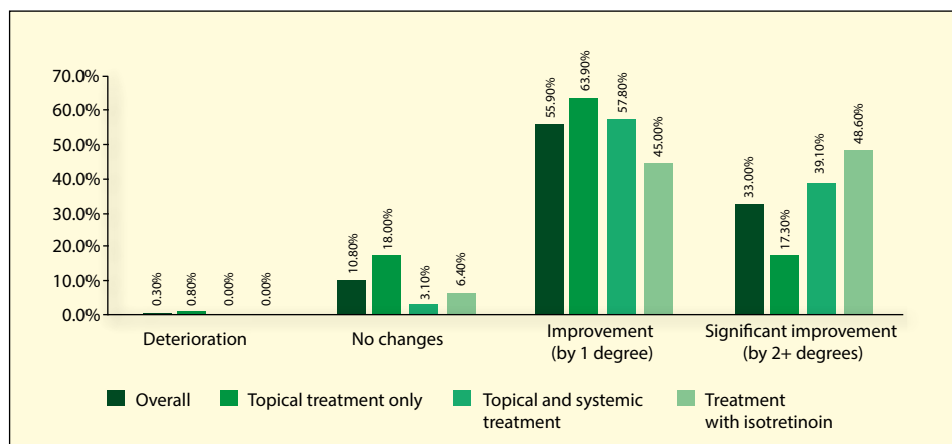


Figure 3. Change in acne severity — overall improvement in GEA score

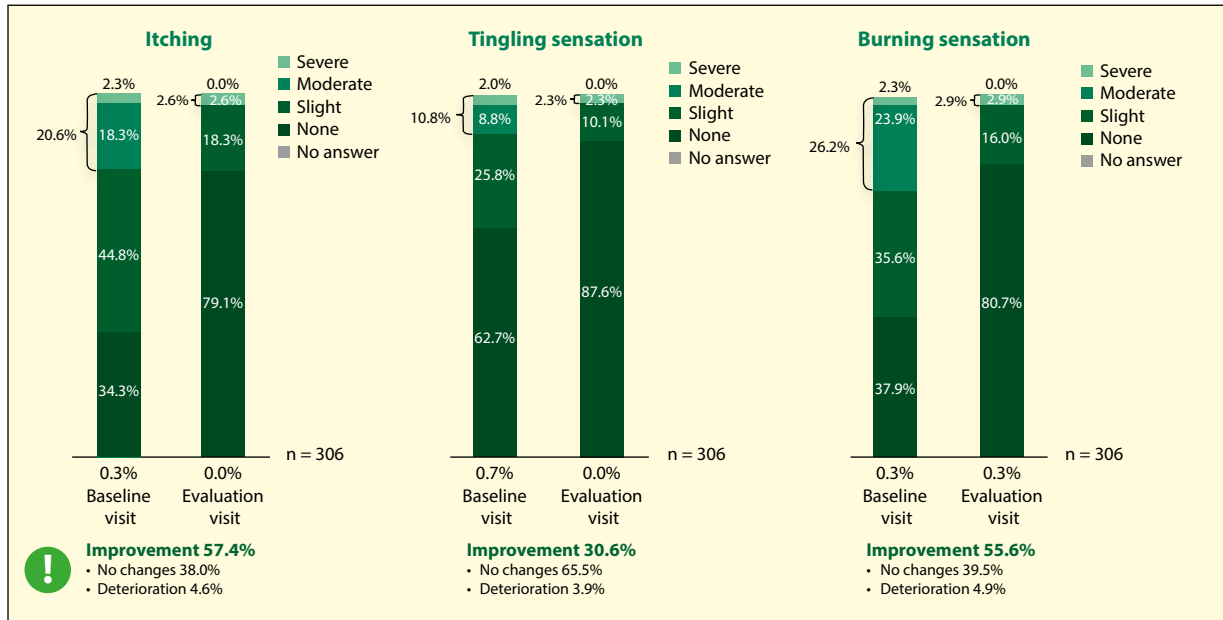


Figure 4. Reduction in pruritus, tingling sensation and stinging at the evaluation visit, according to patients

at the initial visit rated acne as a severe problem, causing them to feel constantly anxious or depressed (46%), negatively impacting their social life (46%), and for 40% of subjects, often causing aggression, frustration, or embarrassment. The treatment resulted in a significant increase in the life quality index. At the evaluation visit, as many as 92% of the respondents admitted that acne was a minor problem or not at all (only 41% during the initial visit). 47% of patients did not feel any discomfort with the appearance of their skin (initially only 9%), 59% did not feel aggressive, frustrated, or embarrassed by their acne (during the first visit 20%), 49% admit that acne does not negatively affect their lives in society (initially 17%). Approximately 70% of respondents felt an improvement in their quality of life in such aspects as feelings related to the appearance of the skin (70%), perception of problems caused by acne (69%), aggressive behaviour or being frustrated (66%), everyday life and relationships with others (65%).

Cosmetic proprieties

The study participants highly rated EFFACLAR H ISO-BIOME care cream and washing cream (Fig. 5, Fig. 6). According to the patients, the EFFACLAR H ISO-BIOME care cream was easy to apply (99% positive ratings) and did not leave an oily layer on the skin (96% positive ratings). In addition, 96% of all respondents rated this product as gentle for the skin, with a pleasant consistency, giving a sense of comfort and not drying the skin. The EFFACLAR H ISO-BIOME washing cream was also positively rated by patients. 97% of respondents claim its formula is pleasant. In 95% of all cases, no shine, greasy layer or skin stickiness was observed after

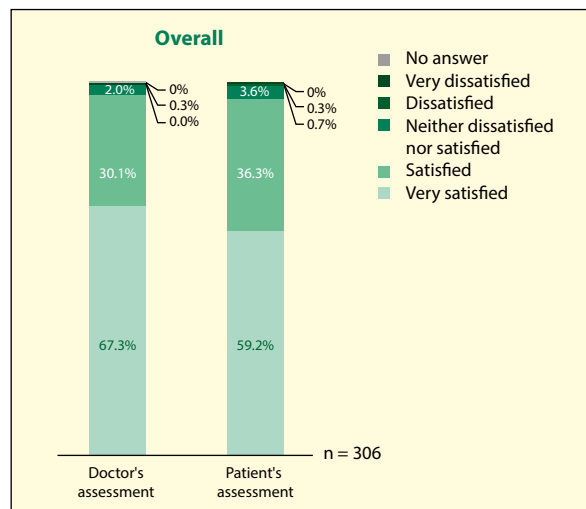


Figure 5. Overall assessment of satisfaction from the use of EFFACLAR H ISO-BIOME preparations

application. The subjects also highly appreciated EFFACLAR H ISO-BIOME washing cream for cleansing (98%) and moisturizing skin (93%) (Fig. 7). The type of treatment regimen did not significantly affect the perception of the effectiveness of EFFACLAR H ISO-BIOME preparations.

DISCUSSION

Nowadays, acne vulgaris is one of the skin diseases most often encountered by dermatologists and primary care physicians. It is estimated that there are 117.4 million incident cases of acne vulgaris globally [6]. One of the main therapeutic problems remains patients' adherence to prescribed acne

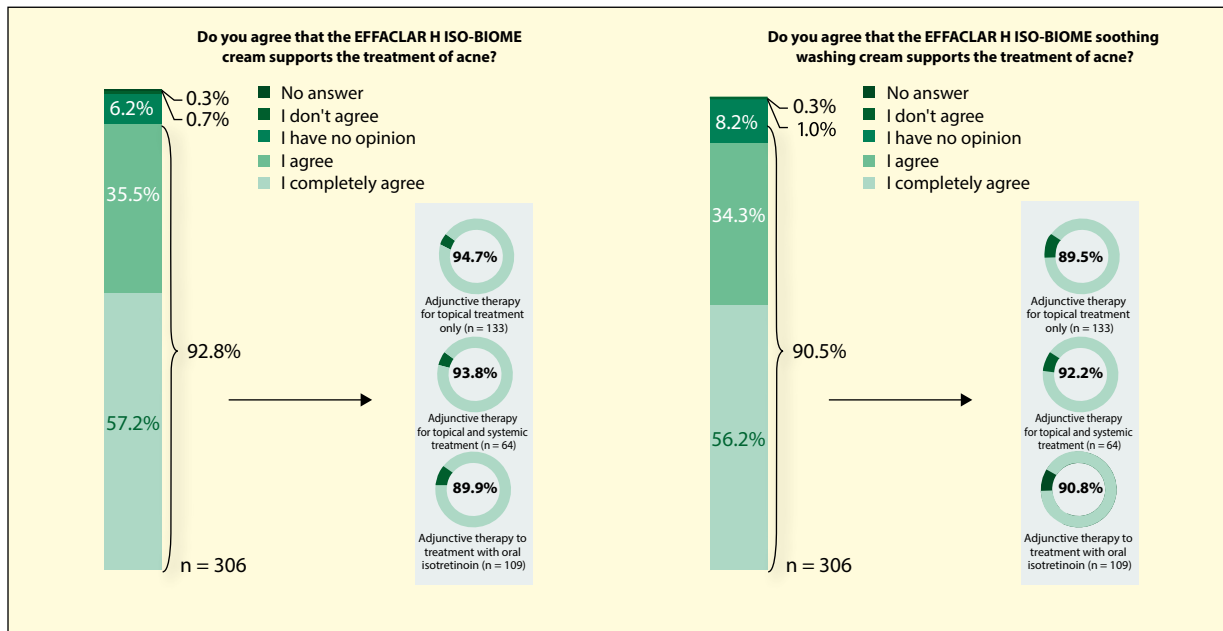


Figure 6. Cumulative satisfaction of patients with EFFACLAR H ISO-BIOME preparations

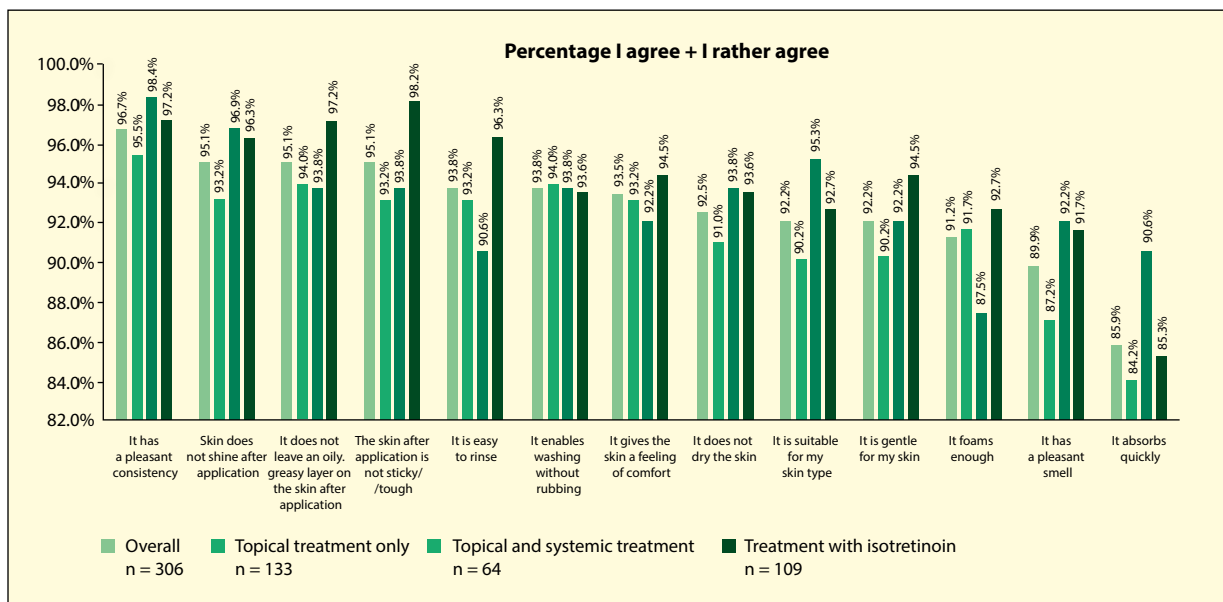


Figure 7. Assessment of cosmetic features of EFFACLAR H ISO-BIOME preparations

treatment regimens [7]. In research conducted by Dréno et al. [8], adherence among acne patients was analysed by the type of treatment (monotherapy with topical agents, combined therapy with topical and systemic agents, and oral isotretinoin). It was shown that side effects such as irritation or dryness significantly decreased adherence and correlated with treatment dissatisfaction. This study also demonstrated that the use of dermocosmetics (moisturizers and cleansers) might have a positive effect on adherence. In our study, both adherence and compliance were high since

EFFACLAR H ISO-BIOME preparations significantly reduced the occurrence and severity of side effects of the prescribed anti-acne treatment regimen. It was especially beneficial during oral isotretinoin therapy, where excessive xerosis is one of the most disturbing side effects.

It has been well known that acne lesions have a major impact on patients' quality of life [9]. Our data indicated that emotional and social problems are frequently reported, which was in concordance with previous studies. Many papers suggested that impairment of quality of life may be improved by appropriate

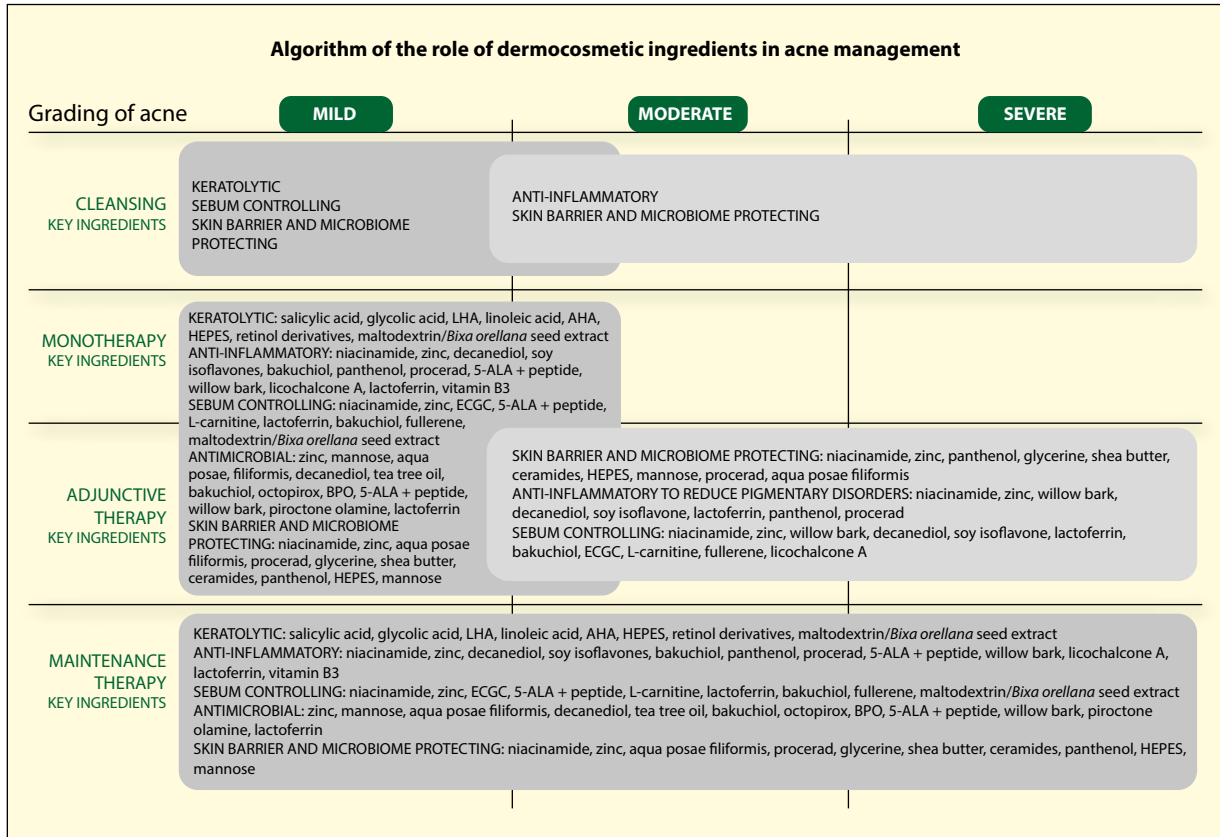


Figure 8. Algorithm of the role of dermocosmetics in acne management; 5-ALA + peptide — 5-aminolevulinic acid + peptide; AHA — alpha hydroxy acid; BPO — benzoyl peroxide; ECGC — epigallocatechin gallate; HEPES — 4-(2-hydroxyethyl)piperazine-1-ethanesulfonic acid; LHA — lipohydroxy acid

acne treatment [10]. In this aspect, adherence to the therapy regimen significantly affects patients' overall well-being. The modern acne treatment strategy requires a holistic and personalized approach that combines conventional therapy with dermocosmetics. In our study, an overwhelming number of patients with different acne subtypes benefited from using EFFACLAR H ISO-BIOME preparations which corresponded with improvement in the life quality index.

Recent studies suggested that altering the cutaneous microbiome may impact the development of acne lesions [11]. Moreover, a systematic review by Lam et al [12], characterized the role of acne treatment in the modification of skin microbiota. It was found that even agents without so-called antimicrobial properties, like topical retinoids may change the composition of the skin microbiome. However, specific active ingredients in dermocosmetics may help to improve skin dysbiosis [13]. The EFFACLAR H ISO-BIOME formula incorporates many active ingredients to improve the skin barrier and restore microbial homeostasis (e.g., Aqua Posae Filiformis, niacinamide, glycerine, or panthenol).

Dermocosmetics containing pharmacologically active ingredients are especially useful in the monotherapy of

mild acne [14]. Nevertheless, they are also an integral part of adjunctive treatment in the management of moderate and severe acne as well as maintenance therapy [15–16]. Targeting specific aspects of acne pathogenesis may help to protect from the formation of new acne lesions [17]. The active ingredients of dermocosmetics may be divided into the following groups regarding their mechanism of action — keratolytics, anti-inflammatory agents, sebum-controlling agents, anti-microbial agents, and skin barrier protection agents (Fig. 8). Careful skin examination is vital to choose maximally effective active ingredients targeting specific skin concerns.

Limitations

Limitations of this study are a relatively short period of observation and discrepancies between the number of patients in each treatment cohort.

CONCLUSIONS

The role of dermocosmetics in the modern acne approach is still growing. This study showed that, regardless of the treatment regimen used, all groups of acne patients

might benefit from using EFFACLAR H ISO-BIOME cream and EFFACLAR H ISO-BIOME washing cream, which was reflected in a significant increase in the comfort of patients' lives. A better understanding of the importance of dermocosmetics as part of a treatment regimen will help to improve adherence and compliance. Continuation of this research is needed to confirm our findings in more extended observation.

Article information and declarations

Data availability statement

Data is contained within the article.

Ethics statement

The study was conducted according to the guidelines of the Declaration of Helsinki.

Author contributions

DK writing — original draft preparation, DK, AR, DW-B, BB-C, MŁ, BZ — review and editing, AR, BB-C, BZ — supervision. All authors have read and agreed to the published version of the manuscript.

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Conflict of interest

DK has been a subinvestigator in clinical trials sponsored by Galderma, AbbVie, LEO Pharma, Argenx, Syneos Health, Celltrion. AR has worked as a consultant or speaker for AbbVie, Bioderma, Celgene, Chema-Elektromet, Eli Lilly, Galderma, Janssen, LEO Pharma, Medac, Menlo Therapeutics, Novartis, Pierre-Fabre, Sandoz, and Trevi, and participated as principal investigator or subinvestigator in clinical trials sponsored by AbbVie, Arcutis, Drug Delivery Solutions Ltd, Galderma, Genentech, Janssen, Kymab Limited, LEO Pharma, Menlo Therapeutics, MetrioPharm, MSD, Novartis, Pfizer, and Trevi. DB-Z is an employee of L'Oréal. BB-C, MŁ and BZ declare no conflict of interest.

Supplementary material

None.

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