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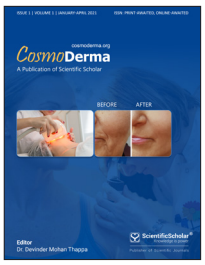

Original Article

Skin moisturizing and anti-acne effect of acne moisturizer in healthy adult subjects with mild-to-moderate acne-an open label, single arm clinical study

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ABSTRACT

Objectives: Acne vulgaris is an extremely common condition that occurs mostly during adolescence. It often causes non-inflammatory lesions (open and closed comedones), inflammatory lesions (papules, pustules, and nodules), and varying degrees of scarring that leads to a negative impact on quality of life. This open label, single arm, and clinical study was conducted to evaluate the effectiveness of acne moisturizer on skin moisturization in adult subjects with mild-to-moderate acne.

Material and Methods: An open label, single-arm, and clinical study was conducted on 36 enrolled healthy male and females aged 18–35 years having acne-prone skin and with mild-to-moderate acne. Acne moisturizer (Venusia Acne) was applied twice daily and safety and effectiveness of test product was assessed before application to post-application on day 15, day 30, day 45, and day 60 at the end of study. All enrolled subjects had undergone clinical evaluation by dermatologist, instruments evaluation, and subjective evaluation on various parameters.

Results: Thirty-one (n = 31) subjects completed all study visits. After using Acne Moisturizer for 60 days, statistically significant ($P < 0.0001$) improvement from baseline was observed in skin moisturization. The product was also found effective in protecting skin barrier function ($P < 0.0001$) by reducing trans-epidermal water loss. Assessment of prevention of appearance of new acne and acne reduction using Investigator's Global Assessment (IGA) Scale for acne vulgaris by dermatologist shows significant improvement from baseline to each study visit and at the end of study. Statistically significant reduction ($P < 0.0001$) in acne severity assessed by IGA was also observed. Moreover, significant reduction ($P < 0.0001$) in skin sebum level, skin blemishes, skin redness, skin pigmentation, and facial pores was also observed as assessed by instruments and 3D image analysis system. Assessment of the subject satisfaction questionnaire and subject response index was also found in parity of the outcome. Furthermore, no adverse event was recorded during the study conduction.

Conclusion: The results of this clinical study suggest that acne moisturizer helps in significantly improving skin moisturization when applied for 15 days onward. It is also safe and effective in aiding reduction of skin sebum level, skin blemishes, skin redness, skin pigmentation, and facial pores; it can be effectively used as an adjunct for management of mild-to-moderate acne prevention and acne reduction, while providing sufficient moisturization to the skin.

Keywords: Acne, Anti-acne, Moisturization, Moisturizing cream

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INTRODUCTION

Acne vulgaris, often known as common acne, is a chronic skin condition that affects more than 85% of young individuals worldwide.[1] Acne vulgaris has lifetime prevalence and can persist into adulthood; however, usually it distresses during adolescence with a 50.9% prevalence rate of acne in women ages 20–29 years and 26.3% in women ages 40–49 years.[2] It is a condition of the pilosebaceous unit and is characterized by the appearance of lesions of the hair follicle and sebaceous gland (a small gland in the skin secretes oil or sebum to lubricate hair and skin). Sebum, the oily secretion of the latter, containing wax esters, sterol esters, cholesterol, di- and triglycerides, and squalene, makes the skin more oily that plays a key role in acne development.[1]

Depending on severity, acne can be classified as mild and moderate that display primary lesions only. The severe acne, on the other hand, also includes nodules, cysts, and eventually open lesions. Acne mostly affects the face but, sometimes it may also affect the back area below the shoulder and even hands and neck. Acne vulgaris causes non-inflammatory lesions, inflammatory lesions, and varying degrees of scarring.[3] Non-inflammatory lesions include open and closed comedones, while papules, pustules, and nodules are types of inflammatory lesions. Although acne does not cause serious long-term health issues, but it may cause emotional distress (including depression, anxiety, low self-esteem, and declined social affiliation) and can harm the skin by residual scarring on the affected area depending on the severity.[3]

Numerous treatment choices are available to treat acne still novel agents continue to be developed to treat the condition.[4] The main goal of acne treatment aims to prevent and lessen the existing inflammatory or non-inflammatory acne lesions, improve appearance, prevent or minimize potential adverse effects, minimize the duration of disorder, and minimize any scarring and morbidity.

Skin dryness may lead to disruption of the outermost layer of the skin, that is, stratum corneum, resulting in transepidermal water loss (TEWL), especially with the use of topical acne treatments such as benzoyl peroxide and retinoid.[5] Moisturizing the skin may reduce extreme dryness or oiliness that causes damage to the skin that further leads to common skin conditions such as acne. A good moisturizing agent helps in maintaining sufficient hydration level and protecting skin barrier function, preventing from production of extra oil that can clog the pores, and leads to more acne breakouts. Moisturizers as adjunctive therapy have proven benefits in enhancing the management of certain dermatologic conditions.[5] Thus, moisturizers are recommended in addition to the primary therapy for acne.[6,7] Depending on mechanism of action, the commercially available moisturizers often use occlusives, humectants, emollients, and protein rejuvenators constituents to provide favorable moisturizing results.[8]

Keeping this in mind, the test product was developed and through this study, we intended to study the safety and efficacy of the product on skin moisturization and anti-acne effect over 8 weeks of use among healthy adult men and women population with mild-to-moderate acne.

MATERIAL AND METHODS

Study design and participants

An open label, single-arm, and clinical study was designed to evaluate the effectiveness of Dr Reddy's Laboratories acne moisturizer (Venusia Acne) on skin moisturization in adult subjects with mild-to-moderate acne. Adult subjects of both sex (preferably with equal numbers) with age between 18 and 35 years (both inclusive at the time of consent) having acne-prone skin and with mild-to-moderate acne were included in the study.

All enrolled subjects had undergone clinical evaluation by dermatologist, instrument evaluation, and subjective evaluation. Safety of the product was assessed throughout the study by monitoring of adverse events (AEs).

There were total six visits in the study, that is,

- Visit 01: Screening visit (within 30 days before day 1)
- Visit 02: Enrolment (day 01)
- Visit 03: Evaluation phase (day 15 ± 02 days)
- Visit 04: Evaluation phase (day 30 ± 02 days)
- Visit 05: Evaluation phase (day 45 ± 02 days)
- Visit 06: Evaluation phase and end of study (day 60 ± 02 days).

Total of 36 subjects were enrolled to get at least 30 completed subjects for evaluation at the end of the study, considering 20% drop out.

Inclusion criteria

Adult male and non-pregnant/non-lactating female subjects in the age group of 18–35 years (both inclusive) at the time of consent, with oily skin having Sebumeter measurement >180 (μg/cm^2) and with acne-prone skin and mild-to-moderate acne condition as per Investigator's Global Assessment (IGA) scale for acne severity were included in the study. Participants, generally in good health, with acne marks/spots and visible pores were included in the study. Female subjects of the childbearing potential must had a negative urine pregnancy test performed on screening visit. Subject who were not under any dermatologic treatment/prescribed medications (except anti-acne treatment/medication) and willing and able to follow the study protocol to participate in the study; willing to use test product throughout the

Table 1: IGA scale for acne severity.

Score	Description
0=Clear skin	No inflammatory or non-inflammatory lesions
1=Almost clear	Rare non-inflammatory lesions with no more than one small inflammatory lesion
2=Mild severity	Greater than Grade 1; some non-inflammatory lesions with no more than a few inflammatory lesions (papules/pustules only, no nodular lesions)
3=Moderate severity	Greater than Grade 1; some-to-many non-inflammatory lesions and possibly some inflammatory lesions, but no more than one small nodular lesion
4=Severe	Greater than Grade 3; some-to-many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions
5=Very severe	Greater than Grade 4; many non-inflammatory and/or inflammatory lesions with some or many nodular lesions

IGA: Investigator's global assessment

study period as instructed; willing to abstain from using any cosmetic product on face, besides the provided products during the entire study course, were some of the other key inclusion criteria. Subjects had to understand and provide written informed consent to participate in the study.

Exclusion criteria

Subjects receiving medications (e.g., steroids or anti-histamines) which would compromise the study or subjects who were receiving topical or systemic treatments (anti-acne treatment was allowed) were excluded from the study. Pregnant or breastfeeding subjects or planning pregnancy during the study period were excluded from the study. Subjects with self-disclosed drug induced acne; undergoing treatment for skin lightening; having history of diabetes, acute cardiac and circulatory diseases, human immunodeficiency virus, hepatitis; using other marketed skin lightening products during the study period or in the past 6 weeks; having any active dermatological skin diseases (e.g., psoriasis, atopic dermatitis, rosacea etc.), that might interfere with clinical assessments; any pigmentary disorder including freckles and melisma; chronic illness which may influence the cutaneous state; and subjects with known allergy or sensitivity to cosmetic products and/or any ingredients of the test product were excluded from the study. Subject with history of drug and alcohol abuse; having excessive hair, moles, open wounds, cuts, abrasions, irritation symptoms, tattoos, scars, sunburn, or any dermatological condition on the test site(s) that can interfere with the reading; subjects who were unwilling to avoid unprotected sun or other ultra violet radiation exposure during the study period; and subjects who had participated in a similar clinical study within the previous 30 days were also excluded from the study.

Test product

The test product (Venusia Acne) by Dr. Reddy's Laboratories was evaluated for its moisturization and anti-acne properties. The acne moisturizer test product is enriched with the plant-based butters and has intense moisturizing potential. All enrolled participants applied approximately 2 g of test product on the entire face twice daily (morning and evening). The test product had to be spread evenly in a circular motion and to be allowed to get absorbed in the skin.

Efficacy endpoints

Primary endpoint of study was evaluation of effectiveness of the test product in improving the skin moisturization using MoistureMeterSC (Delfin Technologies, Finland) from day 01 (before application) to day 15 after product application.

The secondary endpoints included improvement in the skin moisturization using MoistureMeterSC from day 01 (before application) to day 30, day 45, and day 60; change from baseline to day 15, day 30, day 45, and day 60 for prevention in the appearance of new acne and reduction in acne using IGA scale for acne vulgaris [Table 1]; reduction in skin redness using 5-point scale by Dermatologist (0 = *Clear with no signs of erythema,* 1 = *Almost clear; slight redness,* 2 = *Mild erythema; definite redness,* 3 = *Moderate erythema; marked redness, and* 5 = *Severe erythema; fiery redness*); Restoring/Improving the skin barrier function by measuring TEWL using Vapometer (Delfin Technologies, Finland); reduction of skin sebum level using Sebumeter® SM 815 (Courage-Khazaka Electronic, Köln, Germany); effectiveness of test product on acne using Antera 3D analysis system (Miravex Limited, Dublin, Ireland). Subjective assessment using subject satisfaction questionnaire and subject response index about the product after usage at day 15, day 30, day 45, and day 60 were some of the other secondary endpoints.

In addition, some exploratory endpoints were kept for evaluation of effectiveness of the test product in reducing skin pigment using 9-point scale[9] by dermatologist (−4 = *Strongly lighter in color than normal skin,* −3 = *Markedly lighter in color than normal skin,* −2 = *Moderately lighter in color than normal skin,* −1 = *Slightly lighter in color than normal skin,* 0 = *No difference in color than normal skin,* 1 = *Slightly darker in color than normal skin,* 2 = *Moderately darker in color than normal skin,* 3 = *Markedly darker in color than normal skin, and* 4 = *Strongly darker in color than normal skin*); reduction in facial pores using severity scoring scale of individual skin appearance parameters by dermatologist in a severity scale of 0–9 (0 = *None,* 1–3 = *Mild,* 4–6 = *Moderate and* 7–9 = *Severe*) and (0 = *even;*

Table 2: Dermatological assessments.

Dermatological assessments	Visit 02	Visit 03			Visit 04			Visit 05			Visit 06		
	Baseline (SD)	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB
	Mean value												
Prevention of the appearance of new acne (IGA scale)	2.3 (±0.48)	1.3* (±0.48)	−1.0	−44.0	1.0* (±0.00)	−1.3	−55.6	0.7* (±0.55)	−1.7	−70.7	0.5* (±0.51)	−1.8	−78.5
Reduction of existing acne (IGA scale)	2.3 (±0.48)	1.3* (±0.48)	−1.0	−44.0	1.0* (±0.00)	−1.3	−55.6	0.7* (±0.55)	−1.7	−70.7	0.5* (±0.51)	−1.8	−78.5
Assessment of skin redness using 5-point scale	1.8 (±0.56)	0.7* (±0.61)	−1.1	−60.7	0.6* (±0.50)	−1.2	−69.4	0.0* (±0.19)	−1.7	−96.6	0.0* (±0.00)	−1.8	−100.0
Assessment of skin pigment using 9-point scale	1.6 (±0.50)	1.1* (±0.31)	−0.5	−23.2	1.0* (±0.00)	−0.6	−28.3	0.8* (±0.56)	−0.8	−44.8	0.9* (±0.30)	−0.7	−35.5
Assessment of facial pores using severity scoring scale of individual skin appearance parameters	2.9 (±1.16)	1.5* (±0.58)	−1.3	−43.8	1.2* (±0.38)	−1.8	−55.1	0.2* (±0.51)	−2.6	−91.7	0.3* (±0.44)	−2.6	−92.1

*Significance level (P<0.0001). CFB: Change from baseline, SD: Standard deviation, IGA: Investigator's global assessment

Table 3: Instrumental assessments.

Instrumental Assessments	Visit 02	Visit 03			Visit 04			Visit 05			Visit 06		
	Baseline (SD)	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB
	Mean value												
Skin moisturization using MoistureMeterSC	33.04 (±2.26)	48.16* (±2.48)	15.12	46.08	53.14* (±2.45)	20.12	61.54	56.93* (±2.32)	23.97	73.37	59.83* (±2.66)	26.79	81.89
Skin Barrier Function (TEWL) using Vapometer	9.50 (±0.90)	8.71* (±0.67)	−0.83	−8.48	8.19* (±0.55)	−1.30	−13.48	7.81* (±0.52)	−1.70	−17.62	7.46* (±0.54)	−2.04	−21.14
Skin sebum level using Sebumeter® SM 815	215.97 (±11.23)	177.20* (±6.79)	−38.57	−17.74	163.62* (±10.44)	−52.19	−−24.07	149.29* (±10.11)	−66.37	−30.66	139.36* (±10.67)	−76.60	−35.38
Assessment of blemishes using Mexameter® MX 18	564.85 (±53.07)	525.29* (±48.67)	−42.93	−7.49	494.13 (±43.45)	−73.60	−12.87	450.45* (±43.04)	−115.77	−20.40	420.71* (±44.93)	−144.14	−25.45

*Significance level (P<0.0001). TEWL: Trans epidermal water loss, CFB: Change from baseline; SD: Standard deviation

Table 4: 3D image analysis by antera 3D.

3D image analysis by antera 3D	Visit 02	Visit 03			Visit 04			Visit 05			Visit 06		
	Baseline (SD)	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB	Post baseline (SD)	CFB	% CFB
	Mean value												
Assessment of acne (volume of acne [mm^3])	22.90 (±14.68)	21.48* (±13.31)	−2.51	−11.40	17.95* (±12.48)	−4.92	−24.44	16.11* (±11.68)	−7.78	−37.44	12.52* (±11.02)	−10.38	−53.32
Assessment of acne (area of acne [mm^2])	334.04 (±170.84)	329.63* (±164.81)	−19.30	−5.916	298.61* (±161.12)	−35.24	−11.168	292.89* (±148.25)	−54.39	−16.20	258.69* (±137.23)	−75.35	−22.91
Assessment of blemishes (color [L*] of blemish)	52.00 (±6.02)	53.65* (±6.03)	1.79	3.54	55.86* (±6.11)	3.95	7.75	58.10* (±5.96)	6.11	11.98	60.47* (±5.90)	8.47	16.56
Assessment of blemishes (concentration of melanin [a.u.])	60.93 (±8.36)	59.09* (±8.05)	−2.10	−3.42	57.05* (±7.90)	−4.02	−6.57	54.70* (±7.68)	−6.19	−10.18	52.63* (±7.98)	−8.29	−13.75
Assessment of pores (total volume [mm^3] of pores)	3.575 (±1.85)	2.862* (±1.616)	−0.824	−22.551	1.904* (±1.320)	−1.707	−48.050	1.140* (±1.026)	−2.527	−71.520	0.602* (±0.525)	−2.973	−79.577
Assessment of pores (Density [number of pores/mm^2] of pores)	60.956 (±12.85)	55.305* (±11.620)	−4.905	−8.052	51.740* (±11.819)	−9.281	−15.142	46.332* (±10.740)	−13.684	−22.868	42.353* (±11.854)	−18.603	−30.974
Assessment of pores (number of pores [count of pores])	1124.3 (±381.61)	956.5* (±320.13)	−152.0	−12.9	802.7* (±266.85)	−335.8	−27.4	656.9* (±250.15)	−455.7	−39.5	478.1* (±204.41)	−646.2	−55.6
Assessment of pores (porosity index)	2.183 (±0.946)	1.679* (±0.761)	−0.517	−20.414	1.151* (±0.567)	−1.035	−43.281	0.624* (±0.431)	−1.578	−70.082	0.359* (±0.256)	−1.824	−75.561

*Significance level ($P<0.0001$). CFB: Change from baseline; SD: Standard deviation

not noticeable, 1 = no more than 5 pores slightly larger; localized to nose and cheekbone, 2 = *scattered number of pores lightly distributed over face,* 3 = *few large pores visible; moderate number localized to one area,* 4 = *moderate number in several areas,* 5 = *moderate number in many areas or severe number in few areas,* 6 = *few periorbital comedones* [*4 or less*], 7 = 5–10 *periorbital comedones,* 8 = 11–15 *periorbital comedones, and* 9 = *numerous periorbital comedones* >15); reduction/lightening of blemishes using Mexameter® MX 18 (Courage and Khazaka, Germany) and effectiveness on blemishes and pores using 3D analysis system at day 01 (before application) to day 15, day 30, day 45, and day 60. Monitoring of incidence of undesirable/AEs, if any, was also recorded as safety endpoint throughout the study.

Statistical analysis

All statistical tests of the recorded data were done using SAS® statistical software (Version: 9.4; SAS Institute Inc., USA). Continuous variables were summarized using tables of descriptive statistics (i.e., number of subjects with recorded observations, mean, standard deviation, median, minimum, and maximum). Categorical variables were summarized using counts and percentages. For continuous variables, the within-treatment analyses were conducted to compare baseline to post-treatment data using paired *t*-test. For categorical variables, the within-treatment analysis was conducted to compare baseline to post-treatment analysis using Wilcoxon signed rank test. The data of subjects, using anti-acne product other than the test product, were analyzed separately. Any AEs, if any, were summarized with a number and the percentage.

Ethics

The clinical study was conducted in compliance with the ethical principles and guidelines that originate in the Declaration of Helsinki and in accordance with The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use-good clinical practice (GCP) (E6 R2) for GCP.

Prior approval on Study Protocol (C3B02408; DRL-IND-GGI-029-ACNE/2022) and study documents including informed consent document (ICD) had been taken from ethics committee on August 29, 2022. The trial was registered on September 12, 2022, with Clinical Trial Registry of India (CTRI) (CTRI/2022/09/045434).All necessary approvals were obtained prior to commencement of study. The subjects were screened only after ICD presentation and obtaining signed approval from them. Details of the test product being evaluated were also explained by the investigator including possible side-effects, allergies, and other expected reactions.

RESULTS

Subject disposition and demography

For present study, the sample size was not calculated. It was taken into account based on the previous experience of similar study in consultation with the investigator. The study design was considered as single arm to ensure availability of adequate number of subjects for statistical analysis and interpretation at the end of study. In the present study, total of 56 subjects were screened, out of which 41 subjects passed in the screening whereas, 15 subjects were screening failed. Out of screening passed subjects, 36 subjects fulfilling all inclusion criteria were enrolled in the study, with average (±standard deviation) age of 26.4 (±4.72) years. Among 36 enrolled subjects, five subjects were withdrawn due to lost to follow-up and excluded from the study. Total of 31 subjects completed all study visits as per the study design and data were recorded and analyzed for all study completed subjects.

Dermatological assessment

Assessment of prevention and reduction of acne using IGA scale for acne vulgaris

Acne moisturizer significantly decreased score of IGA Scale of acne severity by 44.0% on day 15 ($P < 0.0001$), 55.6% on day 30 ($P < 0.0001$), 70.7% on day 45 ($P < 0.0001$), and 78.5% on day 60 ($P < 0.0001$), as compared to baseline. There was no increase in the acne severity, proving prevention of new acne appearance. On the other hand, there was significant reduction in IGA score indicating reduction in existing acne severity during the course of the study [Table 2].

Assessment of skin redness using 5-point grading scale

Dermatological assessment of skin redness by 5-point scale showed reduction of mean score of skin redness from 1.8 at baseline to 0.0 on day 60 at the end of study. A significant reduction of 60.7% on day 15 ($P < 0.0001$), 69.4% on day 30 ($P < 0.0001$), 96.6% on day 45 ($P < 0.0001$), and 100% on day 60 ($P < 0.0001$) was recorded in skin redness [Table 2].

Assessment of skin pigment using 9-point grading scale

Assessment of mean score of skin pigment using 9-point grading scale showed reducing trend from 1.6 at baseline to 0.9 on day 60 at the end of study. In comparison to baseline score, there was significant reduction in skin pigment by 23.2% on day 15 ($P < 0.0001$), 28.3% on day 30 ($P < 0.0001$), 44.8% on day 45 ($P < 0.0001$), and 35.5% on day 60 ($P < 0.0001$), as assessed by dermatological assessment of skin pigment by 9-point scale [Table 2].

Assessment of facial pores using severity scoring scale of individual skin appearance parameters

Dermatological assessment of facial pores severity by severity scoring scale showed reduction of the mean score of facial pores severity from 2.9 at baseline to 0.3 on day 60 at the end of study. A significant reduction in facial pores severity by 43.8% on day 15 ($P < 0.0001$), 55.1% on day 30 ($P < 0.0001$), 91.7% on day 45 ($P < 0.0001$), and 92.1% on day 60 ($P < 0.0001$) was observed [Table 2].

Instrumental assessment

Assessment of skin moisturization using MoistureMeterSC

At baseline, the mean score of MoistureMeterSC was 33.04, which was increased to 33.04, 53.14, 56.93, and 59.84 on day 15, day 30, day 45, and day 60, respectively. There was significant improvement in skin moisturization by 46.08% ($P < 0.0001$), 61.54% on day 30 ($P < 0.0001$), 73.37% on day 45 ($P < 0.0001$), and 81.89% on day 60 ($P < 0.0001$), proving effectiveness of the test product in improving skin moisturization at all time points [Table 3].

Assessment of skin barrier function by measuring TEWL using Vapometer

After applying the test product for 60 days, the mean score of Vapometer (g/h/m^2) was reduced from 9.50 at baseline to 7.46 on day 60. It clinically indicates that there was significant reduction in TEWL by 8.48% on day 15 ($P < 0.0001$), 13.48% on day 30 ($P < 0.0001$), 17.62% on day 45 ($P < 0.0001$), and 21.14% on day 60 ($P < 0.0001$). Acne moisturizer provides a protective layer on top of the skin, thereby reducing the TEWL and maintaining healthy skin condition [Table 3].

Assessment of skin sebum level using Sebumeter® SM 815

Mean score of Sebumeter SM 815 (μg/cm^2) was 215.97 at baseline, which was reduced to 139.36 after 60 days of product application. A significant reduction in skin sebum level by 17.73% on day 15 ($P < 0.0001$), 24.07% on day 30 ($P < 0.0001$), 30.66% on day 45 ($P < 0.0001$), and 35.38% on day 60 ($P < 0.0001$) was observed during the present study. It is evident from the result that acne moisturizer is effective in reducing skin sebum level or skin oiliness [Table 3].

Assessment of blemishes using Mexameter® MX 18

The mean score of Mexameter was 564.85 at baseline, which was reduced to 420.71 after applying the test product for 60 days. There was significant reduction in melanin by 7.49% on day 15 ($P < 0.0001$), 12.86% on day 30 ($P < 0.0001$), 20.40% on day 45 ($P < 0.0001$), and 25.45% on day 60 ($P < 0.0001$), thereby lightening the skin blemishes [Table 3].

Assessment of blemishes, acne, and pores using 3D analysis system

Volume and area of acne

The mean volume of acne (mm^3) measured by 3D Analysis System was reduced from 22.90 at baseline to 12.52 on day 60. There was a significant reduction in the volume of acne by 11.40% on day 15 ($P < 0.0001$), 24.44% on day 30 ($P < 0.0001$), 37.44% on day 45 ($P < 0.0001$), and 53.32% on day 60 ($P < 0.0001$), as compared to baseline [Table 4].

Similarly, the mean area of acne (mm^2) measured by 3D Analysis System was 334.04 at baseline, which was reduced to 258.69 after applying the test product for 60 days. This clinically indicates that there was a significant reduction in the area of acne by 5.90% on day 15 ($P < 0.0001$), 11.17% on day 30 ($P < 0.0001$), 16.20% on day 45 ($P < 0.0001$), and 22.91% on day 60 ($P < 0.0001$). Thus, the test product is effective in reducing volume and area of acne [Table 4].

Color (L) of blemish*

The mean L* value measured by 3D analysis system was increased from 52.00 at baseline to 60.47 on day 60. A significant increase in L* value by 3.54% on day 15 ($P < 0.0001$), 7.75% on day 30 ($P < 0.0001$), 11.98% on day 45 ($P < 0.0001$), and 16.56% on day 60 ($P < 0.0001$) was recorded [Table 4].

Average concentration of melanin (a.u.)

At baseline, the mean value of average concentration of melanin measured by 3D analysis system was 60.93, which was reduced to 52.63 on day 60. There was significant reduction by 3.41% on day 15 ($P < 0.0001$), 6.57% on day 30 ($P < 0.0001$), 10.18% on day 45 ($P < 0.0001$), and 13.75% on day 60 ($P < 0.0001$) in average concentration of melanin [Table 4].

Total volume of pore (mm^3)

Total pore volume measured by 3D analysis system was reduced from 3.57 at baseline to 0.60 on day 60. There was significant reduction in total pore volume by 22.55% on day 15 ($P < 0.0001$), 48.05% on day 30 ($P < 0.0001$), 71.52% on day 45 ($P < 0.0001$), and 79.58% on day 60 ($P < 0.0001$) [Table 4].

Pore density (number of pores/mm^2)

The mean score of pore density measured by 3D analysis system was 60.96 at baseline, which was decreased to 42.35 on day 60 at the end of study. There was significant reduction by 8.05% on day 15 ($P < 0.0001$), 15.14% on day 30 ($P < 0.0001$), 22.87% on day 45 ($P < 0.0001$), and 30.97% on day 60 ($P < 0.0001$) in pore density [Table 4].

Number of pores (count of pores)

The mean count (no. of pores) measured by 3D analysis system was 1124.3, which was decreased to 478.1 after applying the test product for 60 days. A significant reduction by 12.9% on day 15 ($P < 0.0001$), 27.4% on day 30 ($P < 0.0001$), 39.5% on day 45 ($P < 0.0001$), and 55.6% on day 60 ($P < 0.0001$) was recorded in pore count (no. of pores) [Table 4].

Porosity index

The porosity index measured by 3D analysis system was reduced from 2.18 at baseline to 0.36 on day 60. This clinically indicates that acne moisturizer significantly reduced the porosity index by 20.41% on day 15 ($P < 0.0001$), 43.28% on day 30 ($P < 0.0001$), 70.08% on day 45 ($P < 0.0001$), and 75.56% on day 60 ($P < 0.0001$) [Table 4].

Subjective assessment

Assessment of the subject satisfaction questionnaire

Subject satisfaction questionnaire consisted of nine questions and was recorded post using the test product for 15 days, 30 days, 45 days, and 60 days. At the end of study, all subjects (100%) were in agreement that there is a reduction in acne; there are no new acne eruptions; the test product helped in moisturizing their skin; the test product helped in retaining their skin's moisture; the test product helped in reducing the skin sebum level; the test product helped in reducing the severity of visible pores; the test product helped in lightening the blemishes; on using the test product, skin feels soft and supple; and there was complete absence of feeling of any hypersensitivity reactions such as redness, swelling, dryness, burning, rash, and irritation after using the test product.

Assessment of subject response index (perception about product)

Subject Response Index was designed to record participant's perception about test product and consisted of five questions. It was observed that after using the test product for 15 days, 30 days, 45 days, and 60 days, all subjects (100%) reported that the test product is easy to use/apply; and they like the product. All participants (100%) were agreed to strongly agree that the test product gets absorbed quickly; the test product has appealing fragrance; and the test product suits their skin.

DISCUSSION

The three key properties of moisturizers, which are mainly responsible for skin hydration, are said to be occlusive, humectant, and emollient effects.[10] Concomitant use of moisturizers as an adjunctive acne therapy offer therapeutic benefits and improves skin condition, reduce irritation, and inflammation,[11] thus comparatively rapid improvement in the acne and skin condition can be achieved. In the present study, acne moisturizer significantly improved hydration of outermost layer of the skin, that is, Stratum corneum, by 46.08% when used for 15 days. Skin moisturization was further increased to 61.54% on day 30, 73.37% on day 45, and 81.89% on day 60, demonstrating efficacy of the test product in significant improvement in skin moisturization. Thus, acne moisturizer helps impart substantial benefits in acne prevention and reduction of acne severity. A significant reduction in the score of IGA Scale of acne severity by 78.5% on day 60 establishes the benefits of acne moisturizer as an adjunct in effective management. On the other hand, there was no increase in the acne severity, proving prevention of new acne appearance. After 60 days application of acne moisturizer, a significant reduction in skin redness by 100% and skin pigmentation by 35.5% was observed by dermatological assessment of skin redness using 5-point scale and 9-point grading scale, respectively, during the conduction of study.

The measurement of TEWL is an indicator of the integrity of skin barrier function or the skin's ability to retain moisture.[12] Clinical evidences suggest that acne is closely related with functional impairment of the skin barrier. Higher TEWL has been observed in persons with mild-to-moderate acne. A reduction in TEWL or improvement in skin barrier function is beneficial for skin's ability to retain moisture content. Acne moisturizer significantly reduced TEWL from 9.50 at baseline to 7.46 after 60 days application of test product, thus helps in providing a protective layer on top of the skin, thereby maintaining hydration and healthy skin condition.

Sebum secretion is beneficial for providing lubrication to the skin and contributing to a better skin barrier. However, elevated sebum excretion is directly involved in the pathophysiology of acne.[13] Excess sebum production leads to formation of open and closed comedones, papules, pustules, and cysts.[11] In a study to correlate acne, sebum, and facial pores, it was demonstrated that existence of acne is closely correlated with size and higher number of facial pores. Sebum secretion levels also showed a positive correlation with facial pores.[14] In the present study, a significant reduction in skin sebum level by 17.73% on day 15, 24.07% on day 30, 30.66% on day 45, and 35.38% on day 60 was recorded. It is evident from the result that acne moisturizer is effective in reducing skin sebum level or skin oiliness, thus providing beneficial effect on acne reduction. Statistically significant ($P < 0.0001$) reduction in pore volume by 79.58%, pore density by 30.97%, pore count (no. of pores) by 55.6%, and porosity index by 75.56% was also demonstrated after 60 days application of acne moisturizer. Results of dermatological assessment of facial pores severity by Severity Scoring Scale were also in parity, where 92.1% reduction from baseline was recorded for

facial pore severity. Moreover, a significant reduction in the volume of acne by 53.32% and mean area of acne (mm^2) by 22.91% was also recorded by 3D analysis system at the end of study. Thus, acne moisturizer was found effective in helping to reduce the volume and area of acne. Data related to the subjective satisfaction questionnaires and product perception further established the effectiveness of acne moisturizer as an adjunct in management of mild-to-moderate acne.

CONCLUSION

In this open label and single-arm clinical study, DRL's acne moisturizer was evaluated for its safety and effectiveness. The acne moisturizer was found to be safe based on no apparent or experienced discomfort, reactions, or any kind of intolerance or adverse skin reactions or events evidenced in the trial.

Acne moisturizer was found to be efficacious in aiding the skin moisturization within 15 days as evidenced by results of the trial. Its regular application twice daily helps in significantly improving the moisturization of the skin; restoring/improving the skin barrier function; reducing oiliness of the skin; reducing the appearance of existing acne and preventing the appearance of new acne; reducing skin redness; reducing the visibility of blemishes/lightening the blemishes, and reducing the number, severity, and visibility of the pores.

Furthermore, based on the subjective feedback, acne moisturizer effectively helped to reduce the acne, prevent new acne eruptions, moisturize the skin, retain the skin's moisture, reduce skin sebum level and severity of visible pores, lighten the blemishes, and make the skin feel soft and supple. It was sensorially well accepted by the subjects.

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Limitation

This study was limited by limited sample size and non-comparative study design as it was open-label study with no comparative (active control) arm.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Mohiuddin AK. A comprehensive review of acne vulgaris. Clin Res Dermatol Open Access 2019;6:1-34.
2. Collier CN, Harper JC, Cafardi JA, Cantrell WC, Wang W, Foster KW, *et al*. The prevalence of acne in adults 20 years and older. J Am Acad Dermatol 2008;58:56-9.
3. Tan AU, Schlosser BJ, Paller AS. A review of diagnosis and treatment of acne in adult female patients. Int J Womens Dermatol 2018;4:56-71.
4. Tan J, Beissert S, Cook-Bolden F, Chavda R, Harper J, Hebert A, *et al*. Impact of facial and truncal acne on quality of life: a multi-country population-based survey. J Am Acad Dermatol 2021;3:102–10.
5. Lynde C. Moisturizers for the treatment of inflammatory skin conditions. J Drugs Dermatol 2008;7:1038-43.
6. Goh CL, Abad-Casintahan F, Aw DC, Baba R, Chan LC, Hung NT, *et al*. South-East Asia study alliance guidelines on the management of acne vulgaris in South-East Asian patients. J Dermatol 2015;42:945-53.
7. Kubba R, Bajaj AK, Thappa DM, Sharma R, Vedamurthy M, Dhar S, *et al*. Indian Acne Alliance (IAA). Acne in India: Guidelines for management-IAA consensus document. Indian J Dermatol Venereol Leprol 2009;75 Suppl 1:1-62.
8. Gala MY, Snehal SM, Sujeet CN, Rathod RR, Ranjan SA, Avijit CA, *et al*. Effect of plant-based paraben free Venusia max cream on skin hydration in healthy individuals with dry skin. J Clin Investig Dermatol 2021;9:4.
9. Shah S, Chew SK. Efficacy and safety of topical depigmenting agent in healthy human fair skin female volunteers: A single-arm study. J Cosmet Dermatol 2017;17:830-9.
10. Chularojanamontri L, Tuchinda P, Kulthanan K, Pongparit K. Moisturizers for acne: What are their constituents? J Clin Aesthet Dermatol 2014;7:36-44.
11. Lynde CW, Andriessen A, Barankin B, De Gannes G, Gulliver W, Haber R, *et al*. Moisturizers and ceramide-containing moisturizers may offer concomitant therapy with benefits. J Clin Aesthet Dermatol 2014;7:18-26.
12. Kulthanan K, Trakanwittayarak S, Tuchinda P, Chularojanamontri L, Limphoka P, Varothai S. A double-blinded, randomized, vehicle-controlled study of the efficacy of moisturizer containing licochalcone A, decanediol, L-carnitine, and salicylic acid for prevention of acne relapse in Asian population. Biomed Res Int 2020;2020:2857812.
13. Pappas A, Johnsen S, Liu JC, Eisinger M. Sebum analysis of individuals with and without acne. Dermatoendocrinol 2009;1:157-61.
14. Kim BY, Choi JW, Park KC, Youn SW. Sebum, acne, skin elasticity, and gender difference-which is the major influencing factor for facial pores? Skin Res Technol 2013;19:e45-53.

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