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AN OPEN LABEL CLINICAL STUDY TO EVALUATE THE DERMAL SAFETY AND POST-APPLICATION EFFECT OF AN OIL CONTROL MOISTURIZER.

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ABSTRACT
An open label clinical study was carried out to screen the efficacy and safety of an oil control moisturizer containing Policosanol, Aloe vera extract and Niacinamide as its active ingredients. The volunteers of either sex were asked to apply the oil control moisturizer on the face in a circular motion, on cheeks, forehead & Ala of nose once a day for a period of 2 weeks. These volunteers were examined prior to entry into the study and later at seven days interval. Adverse effects, if any, due to application of the oil control moisturizer were noted down. Efficacy of the oil control moisturizer was assessed on the basis of changes in the oiliness and moisturizing effect. Results indicated that the oil control moisturizer was efficacious and was well tolerated. It did not lead to any adverse effects. **Aim:** To evaluate the safety and efficacy of Oil Control Moisturiser in subjects with excess facial oiliness. **Methods:** An open label, Phase III clinical trial, evaluating 17 subjects consisted of 3 sessions: baseline, Day 7 and Day 14 for follow up assessments with application of Oil control moisturiser once daily for a period of 2 weeks. Subjects were asked to fill out Oily Skin Self-Assessment Scale (OSSAS) and Oily Skin Impact Scale (OSIS) survey at the first, second and third sessions. At each visit, the cosmetic appearance of the facial skin was scored and usage of oil pads to wipe out oiliness was recorded for efficacy evaluation. **Results:** The Oil Control Moisturiser showed significant difference in every efficacy parameter at different time points from baseline to end of study as measured by number of oil pads used. From this study, it was evident that application of oil control moisturizer has no serious adverse effects. When applied over a period of 2 weeks, it showed beneficial effects in the form of reduction in shine on skin, improved skin softness, smoothness and moisturizing effect. Overall results were satisfying to the study subjects. Subjects felt that applying oil control moisturizer was beneficial. No subjects experienced any adverse events. **Conclusions:** Fourteen subjects completed the study. Significant control in the oiliness of skin was seen at the end of the study. Application of this oil control moisturizer is beneficial for oily skin to control excess oiliness of the skin. Product compliance was also good.

KEYWORDS: Oil Control Moisturiser, Oily Skin Self-Assessment Scale, Oily Skin Impact Scale, Sebum, Oiliness.

INTRODUCTION
Oily skin (seborrhoea) is caused by excess skin oil (sebum). During puberty, increased androgen levels signal the oil glands of the skin to mature. At this time the body begins producing much more skin oil. During pregnancy and menopause, hormonal imbalances can also upset the oil balance and increase the activity of sebaceous glands.

Oily skin is shiny, thick and dull coloured and has coarse pores and pimples along with other embarrassing blemishes. It is also prone to blackheads. In this type of skin, the oil producing sebaceous glands are overactive and produce more oil than required. The flow of sebum or oil increases during adolescence and starts decreasing with age.

Though antibacterial cleansing lotions are available in the market, natural water based oil-free moisturizers are rare. Therefore an Oil Control Moisturiser has been developed for treatment of facial oiliness to keep the skin supple with anti shine.

Increased secretion of sebum is a common cosmetic complaint in adults which plays a vital role in formation of acne, oily scalp and comedo.[1] A subjects' assessment on their skin type is prone to vary according to the seasonal variations in sebum secretion and can be confusing to determine.[2] Oiliness is evaluated by rating skin surface friction which varies on various parts of face and can be altered by product application. The forehead and nasal regions are oilier than cheeks, and an inverse connection has been observed with respect to perceived oiliness and friction on skin.[3]

Oily skin results from large quantities of sebum filling the follicular reservoir and leaking onto the skin surface.[4]

The Sebumeter® and Sebutape® methods are photometric devices universally used to measure sebum secretion.[6]

Draelos *et al.* conducted a randomized, double-blind, clinical trial, evaluating the effect of 2% niacinamide on facial sebum production. They concluded 2% niacinamide might aid in an improved cosmetic appearance for facial shine reduction, but further studies are necessary to characterize its mechanism of action.[5]

In the present study, the oil control moisturizer used has been formulated with a natural sebum regulator, namely Policosanol. Extracted from sugarcane wax, it is standardized to contain not less than 60% Octocosanol. A number of studies indicate the role of Policosanol in acne management. It is reported that this may be attributed not only to its property of inhibiting *P acnes*, acne causing bacteria, but due to its role in regulating skin sebum levels as well.[12]

A therapeutic option for oily skin is thus targeted to sebaceous glands which effectively treat oily skin. Hence this clinical study on oil control moisturizer is conducted to reduce oiliness of the facial skin.

MATERIALS AND METHODS

Subject Information and Consent

Written and oral information about the study in a language understandable by the volunteer was provided to all volunteers. Each volunteer was informed by the study coordinator, prior to the screening evaluation, of the purpose of this clinical study, including possible risks and benefits and documented the informed consent process in the subject's chart. Prior to entry into the study or initiation of any study-related procedures, the subject read and signed the informed consent form along with the date. Sufficient time was provided for each volunteer to decide whether to participate in the study and all the questions and clarifications regarding the study were clarified by the study coordinator. The subject's willingness to participate in the study was documented in source notes by the study coordinator. The form summarized, in non-technical terms, the purpose of the study, the procedures to be carried out, and the potential hazards.

PARTICIPANTS

Subjects were included in the study if indicated "Yes" to all of the inclusion criteria and "No" to all or any of the exclusion criteria.

Inclusion Criteria. (1) Male and female healthy volunteers ranging in age from 18 to 50 years. (2) Willing to give written informed consent. (3) Agree not to use any other anti shine moisturizer (prescription and over the counter) during or before the course of this study.

Exclusion Criteria. (1) History of hypersensitivity reactions. (2) History of erythema, puritus, urticaria or any other facial or dermal problems. (3) Ablative resurfacing procedures to the face within 6 months of the study initiation. (4) Report of pregnancy or breastfeeding.

OIL CONTROL MOISTURIZER APPLICATION

Volunteers enrolled in the study were asked to apply oil control moisturizer (Batch No. CS/0616/06-07, Manufactured by: Sami labs limited, Bangalore) on the face in a circular motion, on cheeks, forehead & Ala of nose once a day for a period of 2 weeks. The subjects were examined initially and on Day 7 and Day 14 of application of the oil control moisturizer.

TRIAL DESIGN

This non randomized, open label, clinical trial. The sample size of the study was 17. Compliance with study supplement was reviewed at each visit. This was by examination of the returned supplement. The study consisted of 14 days intervention period. Subjects met with the investigational team for screening, Day 7 Day 14.

OUT COME

Primary outcome variable: Dermal safety.

Secondary outcome variable: Reduction in oiliness of facial skin and soothing, smoothing and softening effect.

DATA COLLECTION

Demographic characteristics (Table 1) were obtained, including age and sex of the subjects. After application of the oil control moisturizer, the subjects were reviewed for 2 weeks. During this follow-up, they were examined for any change in skin appearance, oiliness and texture. Adverse events, if any, were noted.

STATISTICAL ANALYSIS

Statistical analyses were carried out using Fisher's exact test to find out the level of significance. Analysis was carried out using Graph Pad Prism software, version 4.01.

ASSESSMENT

At the initial visit, a detailed medical history was obtained by interviewing the volunteers regarding any dermatological problems.

During each visit, the subjects were examined for any visible signs of erythema, pruritus, edema and urticaria. The experience of subjects on application of oil control moisturizer during this study was taken into account. Post-application effect of oil control moisturizer included parameters like skin softness, smoothness of skin and moisturizing effect. These parameters were scored by below mentioned tools.

Assessment tools

- Oily Skin Self Assessment Scale (OSSAS) (Table 4).[9,11]
- Oily Skin Impact Scale (OSIS) (Table 4).[10,11]
- Number of oil absorbing pads used

RESULTS

A clinical study was conducted to evaluate the dermal safety and post-application feel of oil control moisturizer in 17 volunteers (8 male and 9 female). Demographic data of the 17 volunteers who entered into the study are given in **Table 1**. Fourteen subjects completed the study out of 17 enrolled subjects, three subjects have been dropped off from study due to personal reasons. Hence 14 subjects have been considered for analysis. The mean age of the volunteers included in the study was 33.17 ± 8.3 years. Subjects were instructed to apply oil control moisturizer on the face in a circular motion, on cheeks, forehead & Ala of nose once a day for a period of 2 weeks. The subjects were reviewed at initial, 1 and 2 weeks post application to evaluate the dermal safety parameters, which included signs and symptoms such as erythema, edema, pain, pruritus and urticaria. None of the subjects showed any adverse effects after the application of the oil control moisturizer. Post-application effect of the oil control moisturizer was evaluated using parameters like reduction in oiliness of the facial skin, smoothing effect and softening effect. The efficacy attributes (**Table 2 & Figure 1-3**) such as assessing the oiliness of the skin was found to be drastically decreasing with respect to initial visit. The Skin Self Assessment Scale (OSSAS) was also found to be decreasing as anticipated from the preliminary visits to the end of the study. While looking at the Oily Skin Impact Scale (OSIS), we were able to find out a steep decrease in the scoring which was an encouraging result to the end point. Number of oil absorbing pads used for wiping the facial oil reduced drastically on application of product over 14 days duration.

Effects of application of oil control moisturizer on "after effects" were excellent. Skin softness was seen in all the subjects after the application of oil control moisturizer. Skin smoothness and moisturizing effect was observed in 90% of the subjects. All the subjects were of the opinion that the application of oil control moisturizer was beneficial.

From this study, it was evident that application of oil control moisturizer has no adverse effects. When applied over a period of 14 days, it produced beneficial effects in the form of skin softness, smoothness and moisturizing effect.

Table 1: Demographic characteristic

Parameter	Statistics	Number (N=14)
	Mean (SD)	33.176(8.3)
Age (Years)	Median	30
	Min; Max	22 ; 51
Gender, n (%)	Male	06 (42.86)
	Female	08 (57.14)

Table 2: Application Feel of Oil Control Moisturizer (n= 14)

Parameter	Evaluation	Response (%)
Smoothness of skin	Observed	90 (p<0.0001)
	Not Observed	10
Skin Softness	Observed	80 (p<0.0001)
	Not Observed	20
Moisturizing effect	Observed	85 (p<0.0001)
	Not Observed	15
Decrease in oiliness of the skin	Observed	90 (p<0.0001)
	Not Observed	0

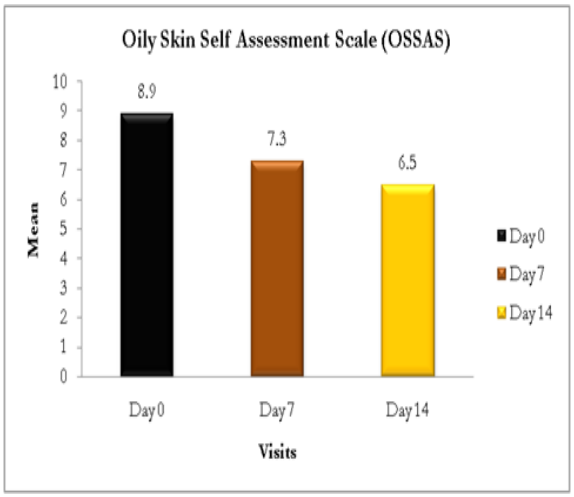

Figure 1: Mean Change in the Oily Skin Self Assessment Scale (OSSAS)

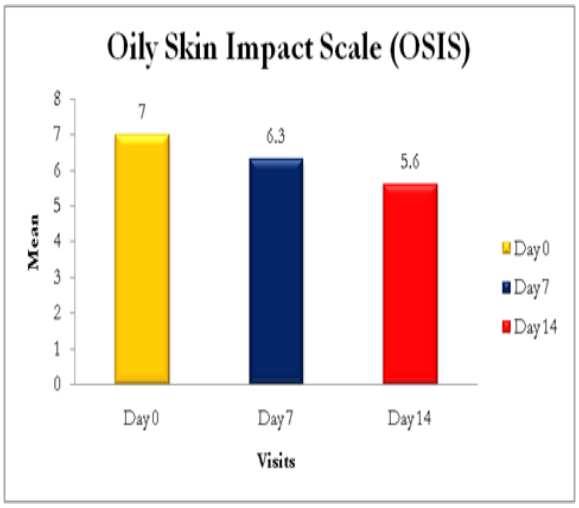

Figure 2: Mean Change in the Oily Skin Self Impact Scale (OSIS)

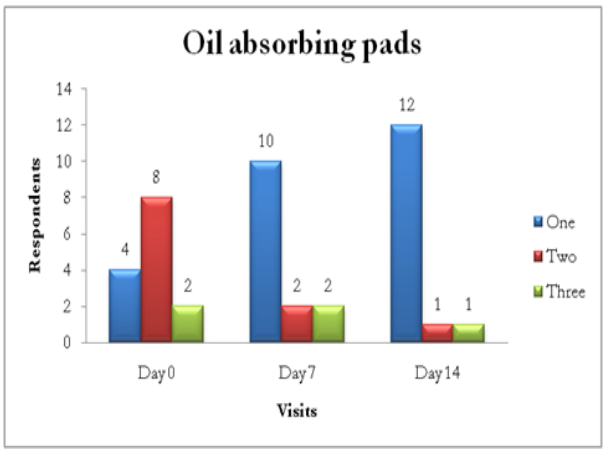

Figure 3: Mean change in the number of Number of Oil absorbing pads used used

DISCUSSION

This study was initiated to evaluate the efficacy and safety of a novel oil control moisturizer. Results of this study indicate that oil control moisturizer is safe and efficacious in soothing and softening the skin.

Irritation and sensitization potential of a cosmeceutical must be determined for local application. The test to determine the irritation and sensitization potential of a product are still at an initial stage of understanding. It is simply diagnosed by observing the skin over which the cosmeceutical has been applied. One needs to look at erythema, oedema, pain and itching as a subjective sign of irritation and sensitization.

Application of this oil control moisturizer is beneficial to people with oily skin to control the oiliness of skin. Beneficial effects seen with oil control moisturizer cannot be attributed to single ingredients and appears to be due to the synergistic effect of all. Policosanol is a mixture of fatty alcohols derived from waxy extract of sugarcane. Policosanol has protective and sebum control properties.[12] Aloe vera juice has antioxidant effect and antimicrobial property.[13] Niacinamide along with its sebum regulating properties has anti-inflammatory properties[14] and antiaging effects such as reduction of solar elastosis.[15]

A further study with larger number of subjects and longer treatment duration is recommended to weigh beneficial effects of this novel oil control moisturizer in regulating excess oiliness.

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