

Clinical and instrumental study of the sebum regulation efficacy of REGU[®]-SEB

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Introduction

Excessively oily facial skin is due to overactive sebaceous glands and can occur in both males and females. The skin is greasy and shiny, with large open pores, feels unpleasant and may be a serious cosmetic problem. Moreover, this type of skin is sensitive and much more prone to acne and seborrhoeic dermatitis. That is why the control over the excessive oiliness is very important.



Oily facial skin

Sebaceous glands activity is stimulated by the androgen hormones. Testosterone arising from the blood circulation is converted in the skin to its more potent form, dihydrotestosterone, by the action of the enzyme 5 alpha-reductase. The inhibition of this enzyme can result in effective reducing sebum production (1).

REGU[®]-SEB is a registered trademark of **Pentapharm Ltd.**, Basel, Switzerland. It is a clear, yellow to orange, slightly viscous solution containing polyphenolrich fractions from the fruits of the North American saw palmetto and South American sesame seeds in a Moroccan argan oil base. This perfectly balanced polyphenol formula, consisting mostly of lignans and phytosterols is designed to control and reduce sebum production.



Saw Palmetto, also known as *Serenoa Serrulata*, is a small palm native to the southeastern United States. Extract made from the fruits of Saw Palmetto is highly enriched with fatty acids and phytosterols. It is used for the treatment of men with symptomatic benign prostatic hyperplasia and male-pattern baldness. Studies have shown that the Saw Palmetto fruit extract prevents the conversion of testosterone to dihydrotestosterone by blocking the activity of the enzyme 5 alpha-reductase and also prevents binding of dihydrotestosterone to androgen receptors (2-6).

Sesamum indicum is a plant native to the East Indies. Now it is found growing in most areas of the world. The oil made from sesame seeds is mostly composed of triglycerides of the unsaturated oleic acid (40%) and linoleic acid (45%), natural antioxidants such as lignans (sesamol, sesamine and sesamol) and tocopherols. It is used as an ingredient in cosmetics because of its anti-free radical, regenerative and emollient properties. The balancing compounds found in this infusion regulate oil production, which in turn helps fight acne and to alleviate either really oily or really dry skin (7-8).

Argania spinosa tree is exclusively native to the geographical area of south west Morocco. Argan kernel oil has a fatty acid composition similar to that of sesame oil and is mostly composed of unsaturated triglycerides and vitamin E. It shows excellent anti-oxidative, skin protective, softening and anti-drying properties, and is recommended to reduce dry skin problems and slow down the appearance of wrinkles. The phytosterols in argan kernels are unique in their combination and were already used as a remedy for acne vulgaris in Moroccan folk medicine (9-10).

Objective

The aim of this study was to evaluate the sebum regulation activity of a 2% REGU[®]-SEB containing cream in subjects with oily facial skin using clinical assessment and skin bioengineering measurements.

Subjects and Methods

Subjects

Twenty healthy volunteers (9 male, 11 female, mean age 36±11 years, range 17-50), 16 with oily skin and 4 with combined skin, were enrolled in this study after given written informed consent.

The subjects were selected after a preliminary clinical examination, completion of a special questionnaire for determination of skin type and quantitative measurements of skin lipids on the face using [sebumetry](#).

The inclusion criteria were: oily or combined type of skin and casual sebum levels over 220 µg sebum/cm² on the forehead and over 180 µg sebum/cm² on the cheeks ([13](#)).



Test product

Test product was Day Cream AROMA PURE ([Aroma](#), Sofia, Bulgaria), which is a part of the [AROMA PURE cosmetic line for oily skin](#). This oil-free cream-gel contains 2% REGU[®]-SEB, 0.1% Vitamin B6, physical UV filter (Titanium dioxide) and special matting complex.



Clinical assessment

The degree of skin oiliness on the face was assessed using a 5-point scale:

0, normal skin; 1, slightly; 2, easily visible; 3, obviously; and 4, extensive oiliness.

Instrumental assessment

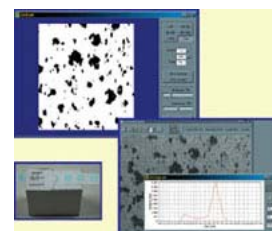
The activity of sebaceous gland on the mid forehead was evaluated using sebum collector foils ([Sebufix F16](#), [Courage+Khazaka](#), Köln, Germany). The foils were applied to the skin surface for 30 s and the absorbed sebum became visible as transparent spots in various sizes. The number and the size of the spots indicated the activity of the sebaceous glands. Then the foils were evaluated with skin camera [Visioscope](#) and software [SELS](#) (Surface Evaluation of the Living Skin). The following parameters were analyzed: the percent area covered by oily spots, the sebum area in square micro meter, the number of oily spots ([14](#)).



Sebufix



Visioscope



SELS

Subjective assessment

A subjective evaluation questionnaire regarding the physical characteristics, tolerance and efficacy of the product was filled out by the subjects at the end of the study.

Study protocol

Two weeks before study begin and during the treatment period the subjects were allowed only the use of regular cleansing products. Approximately 500 mg of the tested product was applied to the face twice daily (mornings: 7:00 to 9:00; evenings: 19:00 to 21:00) over a 4 week treatment period by the subjects at home. The area around the eyes was omitted.

Clinical assessment and measurements of sebaceous gland activity were made before and after the treatment period. Measurements were performed about 18 hours after the last application and minimum 3 hours after the last washing of the skin at controlled room temperature (21-25°C) and relative humidity (28-38%).

Statistical analysis

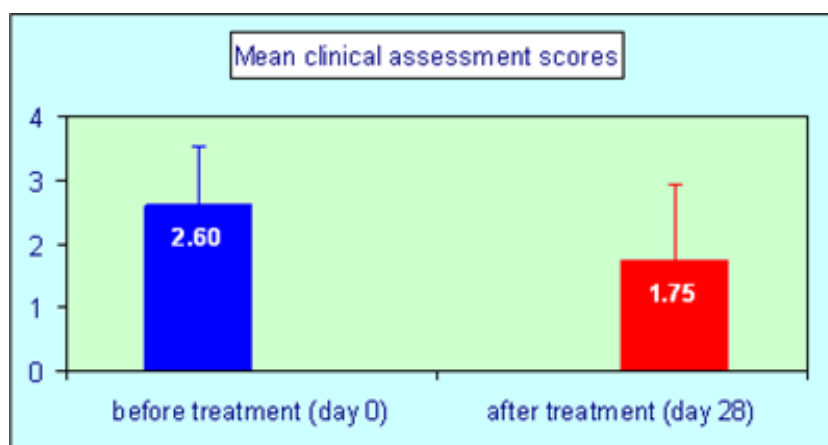
The changes in clinical scores were evaluated using Wilcoxon matched pairs test. The changes in sebaceous gland activity were evaluated using Student's *t*-test for paired data. Values of $P < 0.05$ were considered as statistically significant.

Results

Clinical assessment

All subjects completed the study.

A significant decrease in the severity of oily skin condition was shown by physician's visual assessment after 4 weeks of treatment with test product (33% reduction in mean scores).

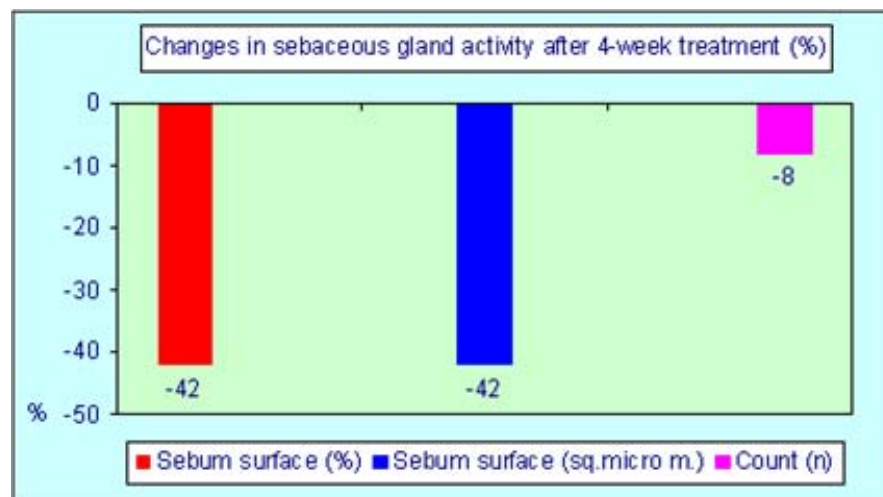


	Before treatment		After treatment		Difference %	P-value
	Mean	SD	Mean	SD		
Clinical score	2.60	0.94	1.75	1.21	- 32.7	$P < 0.0001$

Instrumental assessment

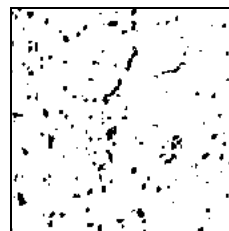
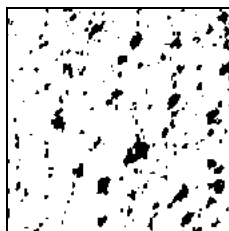
The percent area covered by oily spots and the sebum area in square micrometer significantly decreased by 42% towards the initial values.

The number of oily spots (active sebaceous gland) remained unaltered significantly.



	Before treatment		After treatment		Difference %	P-value
	Mean	SD	Mean	SD		
Area with oily spots (%)	9.7	5.6	5.6	5.1	- 42.1	P<0.001
Area with oily spots (mm ²)	4529.0	2595	2622.5	2400.2	- 42.1	P<0.001
Oily spots count (n)	126.5	43.9	116.3	60.4	- 8.1	NS

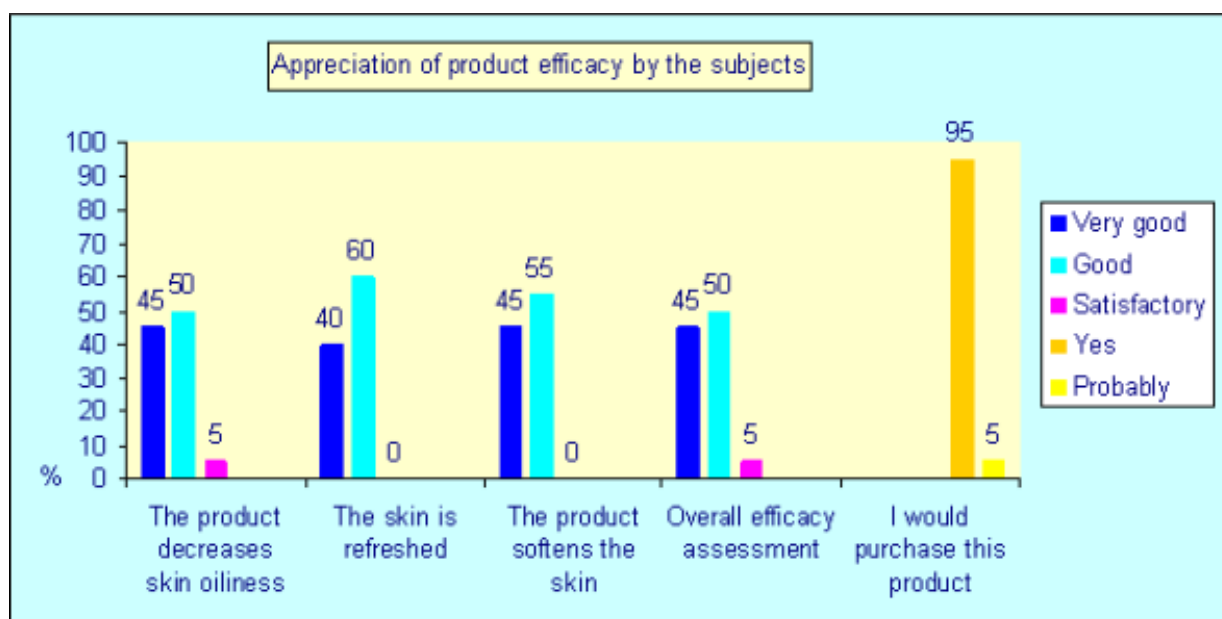
Instrumental assessment - examples



	Before treatment	After treatment
Area covered by oily spots (%)	9.90	5.38
Area covered by oily spots (mm ²)	4619	2509
Oily spots count (n)	189	172

Subjective assessment

The product tolerability and cosmetic properties (colour, fragrance, consistency, distribution, and permeation) were very well accepted by all the subjects. A visible sebum regulating efficacy was reported in 95% of them.



There were no adverse events related to the test product during the study.

Conclusions

- A significant reduction in severity of skin greasiness was found by physician's visual assessment after 4 weeks of treatment with the test product (33% decrease in mean scores).
- A significant reduction in sebaceous gland activity was found using measurements with Sebufix bioengineering technique (42% decrease in area covered with oily spots).
- The product tolerability and cosmetic properties were very well accepted by all subjects. A visible decrease in skin greasiness was reported in 95% of the subjects.
- There were no adverse events related to the test product during the study.

It can be concluded that the tested cream containing 2% of REGU[®]-SEB showed excellent cosmetic properties and very good efficacy in decreasing the severity of skin greasiness as assessed by physician's visual examination, subject's self evaluation and instrumental skin bioengineering measurements. REGU[®]-SEB can be helpful for treatment of skin conditions accompanied by oily skin.

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Synopsis

Title	Clinical and instrumental study of the sebum regulation efficacy of REGU [®] -SEB
Classification	Cosmetic (non-drug)
Background	REGU [®] -SEB is an effectively balanced combination of polyphenols containing high amounts of lignans and phytosterols of plant origin, which regulates the production of sebum to a normal level by inhibiting the 5 α -reductase.
Objective	To evaluate the sebum regulation efficacy of a 2% REGU [®] -SEB containing cream in subjects with oily facial skin
Design	Open study with comparison before and after 4 weeks of treatment
Subjects	20 healthy volunteers (9 male, 11 female), 16 with oily skin and 4 with combined skin, aged 17 to 50 years
Test product	Day Cream AROMA Pure (Aroma, Sofia, Bulgaria) containing REGU [®] -SEB, patent of Pentapharm, Switzerland, Vitamin B6 and UV filters. The product is conformed to Bulgarian cosmetic legislation.
Treatment	Topical treatment of the face with approximately 500 mg/face twice daily by the subjects at home over a 4 week treatment period.
Methods	Clinical assessment and instrumental measurements were performed before and after 4 weeks of treatment. The activity of sebaceous gland on the mid forehead was recorded using sebum collector foils (Sebufix), which were then evaluated with skin camera Visioscope and software SELS (Surface Evaluation of the Living Skin). A self-assessment questionnaire was filled out by the subjects at the end of the study.
Safety assessment	Documentation of adverse events
Results	All subjects completed the study. A significant decrease in severity of oily skin condition was shown by physician's visual assessment after 4 weeks of treatment with test product (33% reduction in mean scores). The area covered with oily spots significantly decreased by 42% towards the initial values (Sebufix and SELS). The number of active sebaceous gland remained unaltered. The product was very well accepted by the subjects. A visible sebum regulating efficacy was reported in 95% of them. There were no adverse events related to the test product during the study.
Conclusion	Dermatologically tested REGU [®] -SEB containing cream showed excellent cosmetic properties and effectiveness on oily facial skin.

Acknowledgements

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