

Studies on Treatment Effects

Dobrev H. Clinical and instrumental study of the efficacy of a new sebum control cream. *Journal of Cosmetic Dermatology* 2007 (in press)

Background: Some botanical compounds are considered useful to reduce sebum production.

Aim: To evaluate the efficacy of a sebum control cream containing polyphenol-rich extract from saw palmetto, sesame seeds and argan oil in subjects with oily facial skin.

Methods: The study was carried out during the winter months (January and February). A total of 20 healthy volunteers (9 male and 11 female, aged 17-50 years, 16 with oily skin and 4 with combined skin) were studied. The test product was applied twice daily to the face for a period of 4 weeks. A clinical assessment and instrumental measurements were performed before and after the treatment period. Casual sebum level on the forehead and both cheeks was determined with a photometric device (Sebumeter). The quantity of sebum on the mid forehead was determined using sebum collector foils (Sebufix), which were then evaluated with skin camera Visioscope and software SELS (Surface Evaluation of the Living Skin). A subjective evaluation questionnaire regarding the cosmetic characteristics, tolerance and efficacy of the product was filled out by the volunteers at the end of study.

Results: The product was very well accepted by all the volunteers. A visible sebum regulating efficacy was reported in 95% of them. After 4 weeks of treatment, the clinical assessment scores decreased by 33%. There was a significant reduction in the casual sebum level by 20% and area covered with oily spots by 42%. The number of active sebaceous gland remained unaltered.

Conclusion: These results objectively and quantitatively demonstrate the efficacy of the sebum control cream tested to reduce the greasiness and improve the appearance of oily facial skin.

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Dobrev H. Treatment of acne with a new topical preparation. Clinical and instrumental study. 15th Congress of the European Academy of Dermatology & Venereology (EADV), October 4-8, 2006, Rhodes, Greece.

Background: Sepicontrol A5 is a cosmetic active ingredient designated to improve the appearance of oily, acne prone facial skin.

Aim: To evaluate the sebum regulation activity, clinical efficacy and safety of a 3% and 4% Sepicontrol A5 containing cream and gel in subjects with mild to moderate acne.

Methods: A total of 19 volunteers were enrolled in this open-labelled study. The test cream and gel were applied to the face and acne lesions respectively, twice daily for a period of 7 weeks. Counting of acne lesions and acne score method were used for clinical assessment before and after 2, 4 and 7 weeks of treatment. Casual sebum level on the forehead and cheeks was determined with a photometric device (Sebumeter). The activity of sebaceous gland on the forehead was recorded using sebum collector foils (Sebufix), which were then evaluated with skin camera Visioscope and software SELS. In addition,

subjective evaluation questionnaire regarding the physical characteristics, tolerance and efficacy of the products and quality of life questionnaires were filled in by the volunteers.

Results: Both products were well tolerated and accepted. A visible improvement was reported in 89% and good to very good clinical response was evaluated in 84% of the subjects. The count of acne lesions decreased significantly by 59% (non-inflammatory - 61%, inflammatory -55%) and the mean clinical assessment scores decreased by 33%. There was a significant reduction in the casual sebum level by 12% and the area covered with oily spots by 27%. The DLQI and CADI mean scores decreased by 46 and 41% respectively.

Conclusion: The offered topical products successfully improve the state of oily acne prone facial skin and raise quality of life of the patients.

Acknowledgements: The author would like to thank Courage+Khazaka, Cologne, Germany for supplying the skin camera Visioscope, tests Sebufix and software SELS, and Solvex Cosmetic Products, Plovdiv, Bulgaria for supplying the preparations.

Dobrev H. Treatment of psoriasis vulgaris with hydrocolloid occlusive dressings in combination with betamethasone dipropionate 0.05% cream. *Scientific Researches of the Union of Scientists – Plovdiv*. Series D. Medicine, Pharmacy and Stomatology, Vol. 1. (Plovdiv) 2002: 103-106.

In the present preliminary study we report comparative results regarding a new method, used for the first time in Bulgaria, for treatment of plaque psoriasis vulgaris. We studied two comparable contralateral plaques in two psoriatic patients. The first plaque of each patient was treated with Lorinden Tar (Jelfa, Poland), contained 1.5% coal tar, 0.02% flumethasone pivalate and 1% salicylic acid, under plastic occlusion for 12 hours daily, 21 days [LT]. The second plaque was treated with 0.05% betamethasone dipropionate cream (Diprosone, Shering-Plough, Belgium) under hydrocolloid occlusive dressing (Varihesive, ConvaTec, Bristol-Myers Squibb, UK), for 7 days, 3 changes [BD+HCD]. Clinical evaluation of skin erythema, induration and desquamation and noninvasive measurements of skin hydration (Corneometer, Courage & Khazaka, Germany) and elasticity (Cutometer SEM 474, Courage & Khazaka, Germany) were made on lesional and perilesional skin before treatment and after 7, 14, and 21 days. After 3-week therapy an equal clinical improvement and increase in water content of psoriatic plaques were observed without any difference between the two methods applied. A significant increase in skin distensibility and decrease in viscoelasticity of the plaques were established. BD+HCD induced maximal improvement of skin mechanics at the first week while LT provoked a gradual improvement with a maximum at the 21 day. Three months later there was not exacerbation of psoriasis.

Dobrev H. Non-invasive monitoring of the mechanical properties of keloids during cryosurgery. *Acta Derm Venereol (Stockh)* 1999, 79 (6): 487-488. [Letter]

Dobrev H. Use of cutometer to assess dermal oedema in erysipelas of the lower legs. *Skin Res Technol* 1998, 4 (3): 155-159.

Background/Aims Inflammatory dermal oedema in erysipelas alters skin mechanics. The aims of this study were to determine the relationship between the skin mechanical properties and the changes in dermal water content in patients with erysipelas of the lower

leg, and to assess the value of measuring skin elasticity in monitoring the effect of therapy.

Patients/Methods Twenty-five in-patients were studied before the treatment and after 10 and 20 days. Visual scoring of oedema, measurements of limb circumference and skin elasticity with a non-invasive, suction device (Cutometer) were made on the affected and unaffected lower legs.

Results Indurated skin was characterized by raised delayed distension (Uv), final distension (Uf), resilient distension (R), viscoelastic to elastic ratio (Uv/Ue) and hysteresis (H) and lower immediate distension (Ue), immediate retraction (Ur), gross elasticity (Ua/Uf) and biological elasticity (Ur/Uf). The visual score of oedema and leg circumference significantly correlated with the increase in Uv, Uv/Ue and H and the decrease in Ua/Uf and Ur/Uf. The large 8 mm diameter measuring probe produced more pronounced changes than the small 2 mm probe. As a result of treatment, a significant reduction in viscoelastic parameters (Uv, Uv/Ue, R, H) and an increase in elastic parameters (Ua/Uf, Ur/Uf) was observed.

Conclusion The non-invasive method applied is suitable for objective assessment of dermal oedema and disease evolution in patients with erysipelas.

Dobrev H., L. Zissova. Effect of ketoconazole 2% shampoo on scalp sebum level in patients with seborrhoeic dermatitis. *Acta Derm Venereol (Stockh)* 1997, 77: 132-134.

Twenty patients with scalp seborrhoeic dermatitis were treated twice weekly with ketoconazole 2% shampoo for 4 weeks. Clinical assessment, culture for *P. ovale* on Dixon broth and lipid measurement at two places were made before treatment and after 2 and 4 weeks. Significant improvement of the severity of seborrhoeic dermatitis ($p < 0.001$) and negative mycological tests by 19 (95%) of patients were observed. The scalp lipid content remained unaltered in 11 patients with an initial lipid value over 220 $\mu\text{g}/\text{cm}^2$ but increased in those with lower initial values. This is probably due to the improvement of sebum delivery onto skin surface as a result of the elimination of the follicular occlusion.

Dobrev H., L. Zisova, R. Yankova. Study of four antidandruff shampoos therapeutic effectiveness. *12th Congress European Academy of Dermatology & Venereology (EADV)*, October 15-18, 2003, Barcelona, Spain.

Background/Aim Treatment of seborrhoeic dermatitis (SD) is directed towards the removal of *P. ovale* and the rest microflora, reduction of skin lipids and suppression of the skin inflammation. The aim of this study was to evaluate and compare the therapeutic effectiveness of 4 antidandruff shampoos containing different active substances.

Materials/Methods A total of 44 patients (32 men, 12 women; aged 15-76 years; 29 with dandruff and 15 with SD) were studied. They were divided into 4 groups treated respectively with shampoo 1 (1% salicylic acid plus 0.5% plant tar plus 3% alcoholic extract of green microalgae), shampoo 2 (1% selenium sulfide), shampoo 3 (1% zinc pyrithione) and shampoo 4 (0.6% ketoconazole plus 1% metronidazole plus 3% sulfur). All shampoos were applied twice weekly for 4 weeks. Clinical assessment and self-assessment of the degree of scalp oiliness, scaling and itching, culture of *P. ovale* on Dixon broth (shampoo 1) and lipid measurement at four sites were made before treatment and after 2 and 4 weeks.

Results Significant improvement of the severity of scalp oiliness, scaling and itching were observed at all patients. Shampoos 2 and 3 showed no significant better clinical

effectiveness. Negative cultures for *P. ovale* were found in 84% of the patients treated with shampoo 1. After treatment, patients with normal initial scalp lipid level (40-100 μ g/cm²) showed increased values, whereas patients with higher initial scalp lipid level (over 100 μ g/cm²) did not show any significant changes. Shampoo 4 most influenced scalp lipid levels - increased values up to the 148 %, and decreased values down to the 9% were observed in group 1 and group 2, respectively.

Conclusion Dandruff and scalp SD can be successfully treated with shampoos containing different active substances. In patients with dry seborrhoea an increase in scalp lipid level occurs due to the elimination of follicular occlusion and improvement of sebum delivery.

Dobrev H. Влияние на телегаматерапията върху физиологичното състояние на кожата. [Influence of telegammatherapy on the skin physiology] **7th National Congress of Dermatology and Venereology**, Sofia (Bulgaria), May 11-13, 2000. Abstracts, pp 28.

Dobrev H. Study of human skin mechanical properties by means of cutometer. [Review] **Folia Med (Plovdiv)** 2002, 44 (3): 1-5.

Aim Cutometer is a commercially available non-invasive suction skin elasticity meter. The purpose of the present article is do discuss some aspects of the biological informativeness and interpretation of the results obtained under studying of skin mechanical properties with cutometer.

Methods/Results Results of previously published in the literature studies on the mechanical properties of healthy and diseased skin and their changes after external influences are analyzed

Conclusion The cutometer method of investigation gives an objective and meaningful information on the mechanical properties of healthy and diseased human skin.