

Beneficial Effects of a New Lip Balm in Patients with Cheilitis Sicca, Lip Lick Eczema and Dry Lips due to Isotretinoin Therapy

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Abstract

Cheilitis is a common dermatological disease affecting children as well as adults. It is related to a variety of causes such as lip licking and atopic eczema, and can also be a side effect of medications (e.g. retinoids). Since lips are known to have a significant effect on the esthetic impression of the face, cheilitis has a considerable impact on patients' emotional well-being and psychosocial interactions.

In the current investigation we assessed efficacy and tolerability of a new lip balm containing licochalcone, panthenol and tocopherol acetate in an open, dermatologically controlled multicenter study in 58 patients. The product was used for 2 weeks at least twice daily on the lips and periorally if needed. Skin compatibility and product performance were evaluated by the physician via visual assessment after 2 weeks. Additionally, tolerability and product characteristics were assessed by the patients at the end of the study.

According to the dermatological evaluation more than 90% of the patients demonstrated improved or even symptom-free skin conditions at the end of the study: Severity of all relevant symptoms such as dryness, scaling, erythema, rhagades, burning and itch decreased significantly. Tolerability of the product was almost exclusively assessed as "very good" or "good". Patients' feedback was completely in line with the physicians' evaluation. Especially tolerability, compatibility with medical therapy and suitability for sensitive skin were rated extremely high. Consequently most patients were in favor of using the product and the physicians recommended the product in almost all cases.

Our data demonstrates that the new lip balm is a highly effective and tolerable product which is especially suited in the management of patients with cheilitis due to atopic eczema or retinoid therapy.

Introduction

The appearance of lips has a significant effect on the esthetic impression and on the overall attractiveness of the face (1, 2). Thus cosmetics for beautifying and protecting the lips are of special importance (3). Lips are covered by a thin stratum corneum made of orthokeratotic cells (4) and have poor barrier function and low water holding capacity (5). In fact, water loss of lips in healthy individuals is almost 3 times as high as on the cheeks and measured TEWL values are almost comparable to those of intensively but not completely tape-stripped skin surface (5). Thus, lips are highly vulnerable to environmental challenges such as wind, exposure to cold or dry, hot climate and open-mouth breathing (6) which further enhance water loss and often result in an inflammatory reaction of the skin (irritant cheilitis). Besides being caused by exogenous factors, cheilitis is a common problem in patients suffering from atopic eczema (7), anorexia nervosa (8) or diseases associated with xerostomia such as Sjogren's syndrome (9-11). Furthermore, cheilitis is a common side effect of oral treatment with retinoids (12, 13). Since cheilitis has a considerable impact on patients' emotional well-being and psychosocial interactions a product for the effective treatment of cheilitis would be a real benefit for these patients.

Study objective was to gain further experience regarding efficacy and tolerability of a new Lip Balm (Eucerin®, Beiersdorf AG, Hamburg, Germany) in patients with dry, chapped lips.

Materials and Methods

Subjects

58 subjects with dry, chapped lips were enrolled in this open, dermatologically controlled multicenter study. One patient was lost to follow-up; thus, data of 57 patients were available for tolerability analysis. This panel included 16 patients diagnosed with cheilitis sicca (of which 7 patients had a history of atopy), 18 patients - predominantly children 12 years or younger - with lip lick eczema (of which 9 suffered from atopic dermatitis) and 13 patients receiving treatment with isotretinoin. Since 2 patients stopped using the product within the first week of treatment (reasons: 1x lack of tolerability; 1x product was "too sticky"), 55 patients were eligible for efficacy analysis.

Preparations and application

The lip balm containing licochalcone, evening primrose oil, panthenol, and tocopherol acetate was used for two weeks. The patients were instructed to apply the product at least twice a day to the lips and periorally, if necessary. The study was conducted from November 2005 until April 2006 at two sites in Germany. No other lip care products were allowed to be used during the study period.

Evaluation criteria

At baseline lips were assessed by physicians with respect to dryness, scaling, tension, rhagades, erythema, itching, burning and severeness of these parameters was rated on a 5-point scale (0=none, 1=slight, 2=moderate, 3=severe, 4=very severe). After using the product for approximately 2 weeks, the lips were re-assessed based on the same above given symptoms and the physicians gave a global assessment of the skin condition (symptom-free, improvement, no change, and deterioration). Furthermore, skin compatibility of the product

was rated on a 5-point scale (1=very good, 2=good, 3=satisfactory, 4=moderate, 5=poor). In addition to the dermatologist's assessment the patient was asked at the final visit about his/her assessment of the general skin condition, the tolerability of the tested product, and about its specific properties. Additionally, the desire to keep using the product after the end of the study was documented.

Results

Efficacy of product

Cheilitis-related symptoms markedly decreased during the 2 week study period (fig. 1 and fig. 2a). Improvement rates were statistically significant for all symptoms ($p < 0.0001$, 2-sided t-test), ranging from 75.0% (scaling) and 75.9% (rhagades) to 92.3% and 93.8% for burning and itching, respectively (fig. 2b). A subgroup analysis for patients with cheilitis sicca, patients with a lip lick eczema, and patients receiving isotretinoin was in accordance with the observations made in the whole study population (tab. 1). All in all, more than 90% of all patients demonstrated with an improved or symptom-free skin condition after 2 weeks of using the lip balm.



Figure 1: Representative photographs taken from a patient at baseline and 2 weeks after using Eucerin® Lip Balm

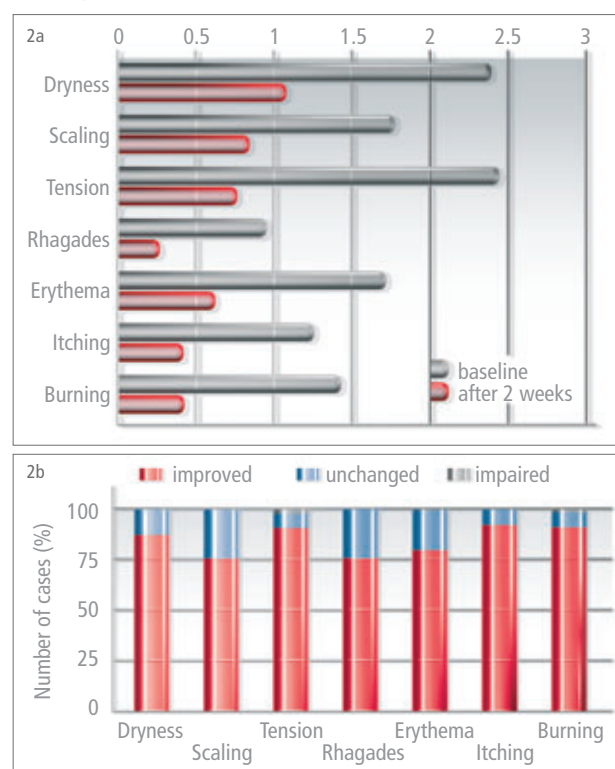


Figure 2: Changes in symptom scores from baseline to end of study (2a, top) and improvement in patients with baseline symptoms (2b, bottom)

Skin Condition	Group of patients					
	Cheilitis only		Lip lick eczema		Isotretinoin	
	N	%	N	%	N	%
symptom-free	2	12.5	0	0	2	15.4
improved	13	81.2	15	93.8	10	76.9
unchanged	1	6.3	0	0	1	7.7
impaired	0	0	1	6.3	0	0
total	16	100	16	100	13	100

Table 1: Physicians evaluation of overall skin condition in different patient subgroups

Skin compatibility

The skin compatibility of the product was evaluated by the dermatologists predominantly as "very good" (73.7%) or "good" (19.3%). Again, a subgroup analysis for patients with cheilitis sicca, patients with a lip lick eczema, and patients with an isotretinoin therapy showed comparable results. Tolerability rating by the patients was completely in line with the physicians assessment (fig. 3). The lip balm was assessed almost exclusively to be "very good" (66.7%) or "good" (22.8%).

Product characteristics

Patients' satisfaction with the performance of the product was very high as well, mostly with mean scores of 5.5 or higher on a 7-point scale. The highest scores were obtained for the compatibility with medical therapies, suitability for sensitive skin and skin tolerability (fig. 4).

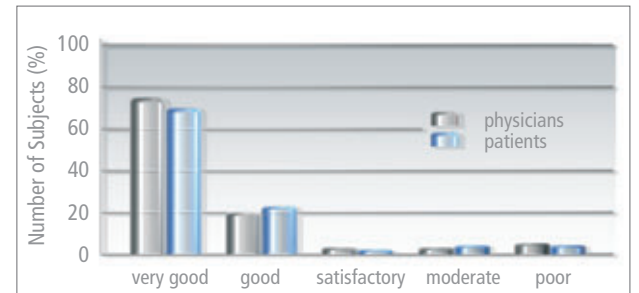


Figure 3: Assessment of skin tolerability by physicians and patients

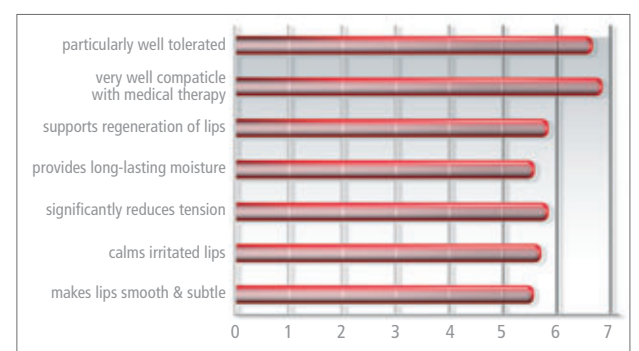


Fig. 4: Patients evaluation of product properties and cosmetic performance (mean values)

Overall assessment

Overall, patients and investigators were very satisfied with the tested Eucerin® Lip Balm. 84.6% of patients rated the tested product to be better than the one they had used before. A further recommendation of the product use was given in 53 of the 57 analyzed cases (93.0%) and 50 patients (87.7%) were in favor of using the product after finishing the study.

Discussion and Conclusion

Cheilitis is a common dermatological disease which is related to a variety of causes such as physical stressors (e.g. wind, low ambient humidity) and certain diseases (e.g. atopic dermatitis, anorexia nervosa). It is also the most common side effect of oral retinoids (14). Actually, cheilitis occurs in virtually all patients on isotretinoin (12). A comprehensive study that included patch testing in 75 cases of cheilitis revealed that 27 (36%) cases were due to irritancy e.g. lip licking, 19 (25%) to allergic contact dermatitis and 14 (19%) to atopic dermatitis (15). A second study conducted in 83 patients with cheilitis or perioral dermatitis in Italy gave comparable results (16). Especially in infants and young children who lick their lips repeatedly, irritant contact dermatitis of lips and the perioral region (lip lickers dermatitis) is frequently diagnosed (17).

Lip balms are considered to be an important part of cheilitis prevention (18) and treatment (19). The results of this study clearly demonstrate that Eucerin® Lip Balm containing licochalcone, evening primrose oil, panthenol, and tocopherol acetate has a very positive impact on the general condition of the lips. All patient groups (cheilitis sicca only, lip lick eczema, isotretinoin) benefited from using the new lip balm (tab. 1). In patients undergoing retinoid therapy the mucocutaneous side-effects of drug-treatment were considerably diminished resulting in an improvement of lip appearance in more than 92% of cases. Even in atopic cheilitis which is difficult to control (20), the number of patients presenting at the end of study with an improved or symptom-free lip condition exceeded 90% (data not shown).

Our data demonstrates that the new lip balm is a highly effective and tolerable product which is especially suited in the management of patients with cheilitis due to atopic eczema or retinoid therapy.

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