

Effective Treatment of Facial Erythema with a Medical Skincare System Containing Licochalcone A

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Abstract

The aim of this multicenter, observational, non-controlled prospective study was to yield data on the properties of a cosmetic skin care system (Eucerin® Redness Relief) in the dermatologist's office. All products (Daily Perfecting Lotion, Soothing Night Cream, Cream Concealer) were developed for patients suffering from facial erythema, couperosis or rosacea and contain soothing Licochalcone A. The lotion and the concealer additionally contain concealing green pigments.

279 patients (82% females, 18% males; mean age 51.1 years) were recruited between August and December 2005 in Germany. The patients presented mainly with erythematous rosacea (59.9%) or papulopustular rosacea (28.3%). The products were dispensed to each patient and were used throughout the study. The observational study period was 35.9 ± 11.2 days with two visits taking place, one at the beginning and one at the end of the study.

At baseline and at the final visit skin symptoms (transient erythema, persistent erythema, skin tension, dryness, papules, pustules and oedema) were rated by the dermatologist on a 5-point scale with 0=absent to 4=very severe. At both visits the quality of life was assessed with a questionnaire. 153 patients used concomitant drugs (64.1% metronidazole, 11.8% azelaic acid) at the beginning, which decreased to 98 patients at the end of the study.

The following improvement rates (based on the number of patients who suffered from the respective symptoms at baseline) were established at the end of the study: transient erythema (68.8%), persistent erythema (76.4%), skin tension (86.1%), dryness (82.6%), papules (71.6%), pustules (76.0%), oedema (80.5%). 3.2% of the patients were free of symptoms, 85.7% experienced an improvement, 7.5% remained unchanged, and only 5 patients perceived a worsening of their skin condition during the study. Tolerability was evaluated for each investigated product: The Day Lotion was rated by the physician to be "very good" or "good" in 93.9%, the Night Cream in 92% and the Cream Concealer in 88.4% of the cases.

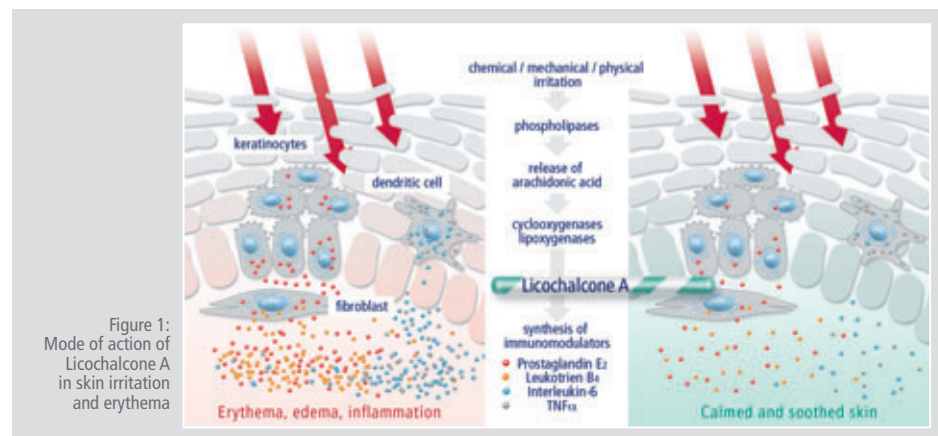
Additionally, 66.8% of the patients positively rated the soothing effect and 65.3% the moisturizing effect of the Daily Perfecting Lotion. 70.9% emphasised the good concealing properties of the Cream Concealer, whereas 81% highlighted the soothing and 83.2% the moisturizing effect of the Night Cream. Eucerin® Redness Relief is an excellent soothing and concealing adjunct treatment for patients suffering from facial erythema, couperosis or rosacea, and also improves the quality of life for these patients.

Introduction

Rosacea is a common inflammatory skin condition reported to affect around 2 to 5% of the adult European population. Patients present with one or more of the following clinically defined subtypes: erythematotelangiectatic, papulopustular, phymatous, and ocular rosacea. Erythema is the most common symptom among individuals with rosacea, which can be persistent, but also flares in response to a number of triggers. These individuals often show sensitivity to skin care products that can cause transient inflammation and subjective symptoms of irritation. Inflammation may aggravate and lead to a progression of the disease; additionally, facial redness can cause discomfort, embarrassment, and concern.

We tested a skin care product regimen for its compatibility in 279 adults with either mild-to-moderate erythematotelangiectatic or papulopustular rosacea or red facial skin attributed to other causes. The regimen included an SPF 15-day lotion and a spot concealer with redness concealing green pigments, as well as a soothing night cream.

All products are formulated with Licochalcone A, a compound derived from the licorice plant *Glycyrrhiza inflata* which recently has been shown to inhibit pro-inflammatory cytokines, eicosanoids, and reactive oxygen species in various types of human skin cells (fig. 1). It has also been observed to relieve post-shave irritation and UV-induced erythema in vehicle-controlled studies. Recently we could also prove that the concomitant application of Eucerin® Redness Relief in patients using metronidazole or azelaic acid did not influence the efficacy of the drug treatment in these patients.



Materials and Methods

279 patients (82% females, 18% males; mean age 51.1 years) were recruited between August and December 2005 in Germany. Three products (Eucerin® Redness-Relief Daily Perfecting Lotion SPF 15, Cream Concealer and Soothing Night Cream) were dispensed to each patient and were used throughout the study. The observational study period was 35.9 ± 11.2 days with two visits taking place, one at the beginning and one at the end of the study.

At baseline and at the final visit skin symptoms (transient erythema, persistent erythema, skin tension, dryness, papules, pustules and oedema) were rated by the dermatologist on a 5-point scale with 0=absent to 4=very severe. At both visits patients completed a questionnaire assessing the degree to which their skin condition affected their quality of life. Table 1 lists these 11 statements and their respective rating scales.

1. The state of my skin is affecting my self respect	1=no, 2=slightly, 3=strongly, 4=extremely
2. Due to the state of my skin I have lower self-confidence	1=no, 2=rarely, 3=often, 4=always
3. Due to my facial redness I need to take medication	1=no, 2=sometimes, 3=often, 4=always
4. Due to the state of my skin I avoid eating and drinking at social events	1=no, 2=sometimes, 3=often, 4=always
5. Due to my facial redness I go out less by daytime	1=no, 2=sometimes, 3=often, 4=always
6. Due to the state of my skin I avoid athletic activities	1=no, 2=sometimes, 3=often, 4=always
7. I feel embarrassed due to my facial redness	1=no, 2=sometimes, 3=often, 4=always
8. Due to my facial redness I avoid social activities	1=no, 2=sometimes, 3=often, 4=always
9. Due to my facial redness I feel uncomfortable to relate with someone	1=no, 2=sometimes, 3=often, 4=always
10. I am worried about my facial redness being in the centre of attention	1=no, 2=sometimes, 3=often, 4=always
11. Due to my facial redness I am less sociable than I would like to be	1=no, 2=sometimes, 3=often, 4=always

Statements 1 and 2 rated with: 1=no, 2=slightly, 3=strongly, 4=extremely
Statements 3 rated with: 1=no, 2=rarely, 3=often, 4=always
Statements 4 to 11 rated with: 1=no, 2=sometimes, 3=often, 4=always
Possible range of sum score from 11 to 44.

Table 1: Quality of Life questionnaire

Results

The most frequent indications were erythematous rosacea/couperosis (59.9%), papulopustular rosacea (28.3%) or facial redness due to laser treatments (9%). 153 patients used concomitant drugs (64.1% metronidazole, 11.8% azelaic acid) at the beginning of the study, which decreased to 98 patients at the end of the study. In total only 15 patients (5.4%) prematurely discontinued the study due to insufficient tolerability (n=3) or efficacy (n=3), and other reasons not directly related to the test products. The presenting symptoms at the start of the study were persistent erythema (94.6%), transient erythema (82.2%), skin tension (76%), skin dryness (74.2%), papules (60.2%), oedema (43.3%) and pustules (38%).

Based on the number of patients who had suffered from the respective symptom at baseline the following improvement rates were calculated: persistent

erythema (76.4%), transient erythema (68.6%), skin tension (86.1%), dryness (82.6%), papules (71.6%), oedema (80.5%) and pustules (76%). Figure 2 shows the evaluation of transient erythema at baseline and the final visit.

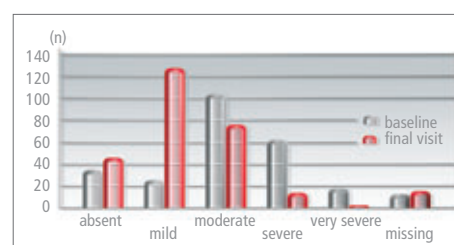


Figure 2: Transient erythema at baseline and final visit

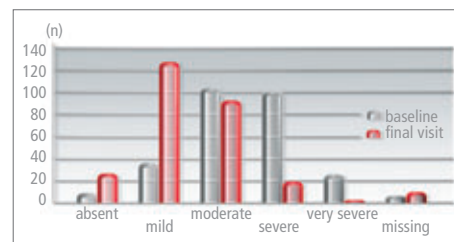


Figure 3: Persistent erythema at baseline and final visit

Figure 4 depicts in a similar fashion the values for persistent erythema.

For each patient the sum score of all symptoms was calculated with a possible range between 0 and 28. The mean value of the sum score decreased by 52.7% from 9.5 at baseline to 4.5 at the final visit. The sum score of clinical symptoms for patients without concomitant treatment decreased from 8.4 at baseline to 3.9 at the final visit. For patients with concomitant treatment the observed decrease was from 10.2 to 5.0. In patients with rosacea the subgroup analysis for the individual symptoms did not indicate any clear trend with respect to the effect of additional medication.

Figure 4 demonstrates the tolerability of all tested products rated by the dermatologists. The Day Lotion was judged "very good or good" in 93.9%, the Cream Concealer in 88.4% and the Night Cream in 92%.

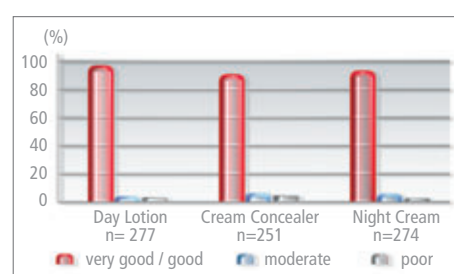


Figure 4: Tolerability, rated by the dermatologist

Figures 5a-c show the rating of the product quality by the patients ranked on a 7-point scale from 1 (=poor) to 7 (=excellent).

In the quality of life assessments, the mean score in 275 patients with evaluation at both visits de-

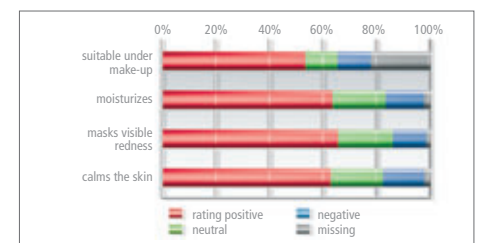


Figure 5a: Product rating by patient; Day Lotion (n=277)

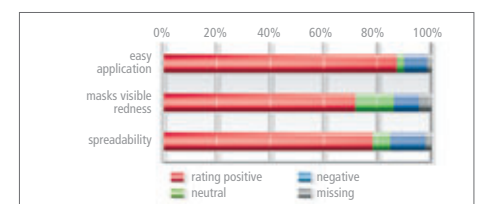


Figure 5b: Product rating by patient; Cream Concealer (n=251)

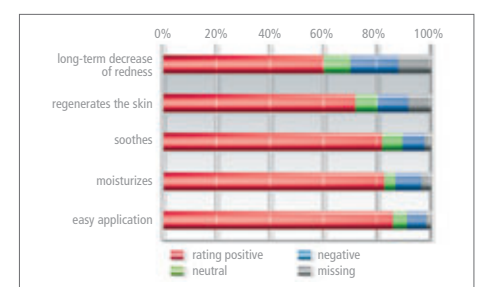


Figure 5c: Product rating by patient; Night Cream (n=274)

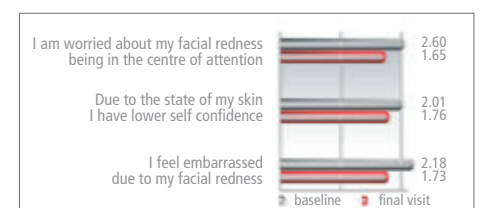


Figure 6: Quality of life questionnaire response, rated on a 5-point scale (0 = not at all to 4 = very much)

Discussion and Conclusion

A recently published clinical study in 62 patients with rosacea and facial redness demonstrated the tolerability of this product regimen as well as the improvement in the quality of life of these patients. Also no negative effect was observed if these products are applied concomitant to metronidazole or azelaic acid in patients with rosacea.

The data assessed in this multicenter clinical study in 279 patients with couperosis, rosacea and erythema after laser treatment demonstrated again the excellent tolerability and efficacy as either an adjunct treatment or medical daily skincare in these indications. At the end of the observation period 85.7% experienced an improvement and 3.2% of the patients were free of symptoms. This positive effect was also reflected by an improvement in the patients' quality of life. The tolerability was judged very good to good in 88.4% (Cream Concealer), 92% (Night Cream) and 93.9% (Day Lotion) respectively. The evaluation of the product qualities by the patients was very positive especially for the camouflaging and soothing effects.

Eucerin® Redness Relief is an excellent soothing and concealing adjunct treatment for patients suffering from facial erythema, couperosis or rosacea and can be used as concomitant treatment for patients undergoing metronidazole and azelaic acid therapy. Additionally our data show that Eucerin® Redness Relief also improves the quality of life for these patients in regard to their self esteem and social interactions.