

# EVALUATION OF A HIGH SPF, HIGH UVA PF SUNSCREEN IN VITILIGO PATIENTS

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## INTRODUCTION

The possibility to attenuate the contrast between vitiligo areas and surrounding normal skin is of utmost importance for vitiligo patients especially during summer in the Mediterranean area. This may improve their quality of life considerably. The objective of our study was to evaluate the effectiveness of a high SPF, high UVA PF, broad band, sunscreen, Anthelios XL (SPF 60+ UVA PF 28 PPD), in vitiligo patients during spring and summer. The effectiveness of the studied sunscreen has been assessed on the basis of its ability to reduce the skin color difference between surrounding normal skin and vitiliginous skin.

**Duration of the study:** the study began in April 2002 and was concluded in October 2002.

## PATIENTS AND METHODS

### Patients

Twenty patients with vitiligo have been enrolled: nineteen females and one male, (mean age 42 ± 8 years, range 29-55 years). Seventeen patients (85%) had skin type III (Fitzpatrick) and 3 patients had skin type IV (15%). Fourteen patients presented with stable disease and 6 with active disease. Patients were also screened by means of a questionnaire to assess their sun exposure habits during the summer period.

### Inclusion criteria:

- symmetrical vitiligo affecting the face and the dorsa of both hands (constantly photoexposed zones);
- skin type III or IV;
- extensive vitiligo was included as long as the face and the hands were symmetrically affected.

### Exclusion criteria:

- treatment with phototherapy or PUVAtherapy during the previous six months;
- face and/or dorsa of the hands totally depigmented;
- presence of spontaneous repigmentation;
- age < 18 or > 60 years;
- skin type I, II, V and VI.

### Product application

Each patient applied the sunscreen on the face and the back of the hands from April to October. The patients were instructed to apply the sunscreens whenever they stayed outdoors for more than 15 minutes, from 9 a.m. to 7 p.m. When staying outdoors for more than two hours they were instructed to reapply the product every two hours. Reapplication was also recommended after bathing or practicing sports.

### Follow-up

The patients were visited every two months after the first visit at inclusion (T0). The visits were respectively: T2, T4 and T6. At each visit the patients have been evaluated clinically and photographs of the treated areas have been taken. Vitiliginous areas have been examined both under natural light conditions and under Wood's light. The presence of erythema or repigmentation on the vitiliginous areas was evaluated. The difference in skin color (pigmentation) between vitiliginous skin and surrounding skin has also been evaluated by means of cutaneous reflectance measurements with a Mexameter MX16 (Courage & Khazaka, Germany) dermaspectrometer. Erythema and pigmentation intensity are expressed respectively as Erythema Index (EI) and Melanin Index (MI) in arbitrary units.

The photographs have been revised by an independent observer that attributed to each body site, and for each visit, a clinical score taking into account the difference in pigmentation between vitiligo areas and normal skin, as follows: marked difference in pigmentation = 3; moderate difference in pigmentation = 2; slight difference in pigmentation = 1; 0 corresponds to a total absence of difference in color between healthy zones and zones with vitiligo, as can be evaluated by the human eye.

Statistical evaluation: the differences between the visits have been evaluated with the ANOVA test.

## RESULTS

One patient dropped out from the study after the second visit due to lack of compliance in product application. Two patients did not come to the final visit (T6), for reasons inherent to their professional activity. No side effects were noted on the sites where the sunscreen was applied. The sunscreens did not have apparently any influence on disease activity but their use almost completely inhibited the appearance of repigmentation on the affected areas.

### Sun exposure habits

The results of the questionnaire on sun exposure habits, that the patients had to fill at each visit, are summarized in table 1. The survey demonstrated that all the patients were exposed daily for more than 1 hour to the sun and for a minimum of 10 days per month, during all the period of the study.

This questionnaire was aimed at determination of the daily mean exposure time during the period before the visit, expressed as sun exposure hours per day.

**Table 1:**  
Characteristics of the patients and sun exposure habits.

Patient	Age	Sex	Skin type	disease activity	T2 sun exposure		T4 sun exposure		T6 sun exposure	
					hrs/day	Days	hrs/day	Days	hrs/day	Days
1	55	F	III	stable	3.4	13	1.5	10	1.3	12
2	38	F	III	active	4.2	16	2.7	17	1.6	15
3	52	F	III	active	3.1	12	4.3	21	2.2	13
4	55	F	IV	active	2.3	14	3.3	14	1.8	10
5	46	M	III	stable	3.5	13	-	-	-	-
6	49	F	III	stable	3.2	15	3.8	20	1.5	11
7	36	F	III	stable	2.4	10	4.6	21	1.3	12
8	34	F	III	active	1.3	14	3.9	17	1.4	10
9	31	F	III	active	2.5	13	3.6	19	1.7	15
10	30	F	III	stable	4.7	20	2.2	12	1.2	10
11	43	F	IV	stable	2.4	15	4.4	17	1.7	11
12	47	F	III	stable	1.8	10	3.8	24	1.9	12
13	29	F	III	stable	2.7	15	5.4	21	2.3	13
14	39	F	III	active	1.6	12	4.3	22	2.2	10
15	43	F	III	stable	2.2	15	4.1	25	1.3	11
16	49	F	III	stable	2.8	16	3.5	22	1.1	13
17	44	F	IV	stable	4.2	23	3.1	17	1.3	15
18	34	F	III	stable	2.7	21	3.3	18	-	-
19	53	F	III	stable	2.1	18	3.7	23	1.7	15
20	40	F	III	stable	2.5	16	3.2	14	-	-

### Instrumental evaluation (skin reflectance)

#### - Face

As regards the face, in all patients there was an overall progressive decrease in the difference in pigmentation as measured with the derma spectrometer between healthy skin and vitiliginous skin. Table 2 shows the values of the MI on unaffected skin (US) and vitiliginous skin (V) as well as the differences between US and V, defined as  $\Delta MI$ . The difference in MI at the various visits did not show statistically significant variations during the treatment.

**Table 2:**  
Melanin index measured on the face at the various visits

Visit	Unaffected skin (US)	Vitiliginous skin (V)	$\Delta MI$ : US - V
T2	492 ± 13	473 ± 10	19 ± 12
T4	491 ± 15	473 ± 11	17 ± 13
T6	491 ± 16	472 ± 12	20 ± 11

#### - Hands

On the contrary, as regards the hands there was a highly significant statistical difference in MI between T0 and T2. This difference became even more evident at T4 and T6.

**Table 3:**  
MI measured on the hands at the various visits

Visit	Unaffected skin (US)	Vitiliginous skin (V)	$\Delta MI$ : US - V
T0	502 ± 15	454 ± 9	48 ± 18
T2	503 ± 16	452 ± 9	51 ± 20
T4	501 ± 14	452 ± 10	50 ± 15
T6	499 ± 11	452 ± 11	46 ± 10

#### - Comparison of hands at visits T2, T4 and T6

The MI was significantly reduced on hands but only on unaffected skin.

The MI varied significantly at T4 and at T6.

The ANOVA for repeated measurements shows an interaction between visit and treatment.

### Clinical evaluation

On the face no statistically significant differences in the clinical score have been noted between T0 and the following visits. On the contrary a highly significant statistical difference has been remarked on the hands: the score became progressively higher in the hands during the treatment period. This corresponds to a reduction in skin pigmentation on the healthy skin.

**Fig. 1a-1b**



**Fig. 2a-2b**



**Fig. 3a-3b**



## DISCUSSION

We consider that the total duration of the study (6 months) and the fact that during these months the climate in central Italy allows prolonged sun exposure has permitted the exposure to a sufficient UV dose, that in the absence of adequate photoprotection can stimulate and maintain pigmentation. The questionnaire on solar exposure demonstrates that the majority of patients are exposed for longer times during the day and for a higher number of days per month during the central period of the study (evaluation at T4) that corresponds to the months of July and August (table 1). This is the period more at risk for vitiligo patients to develop antiaesthetic contrast between affected and normal skin. It must also be considered that in the Mediterranean countries it is not easy for the patients to strictly avoid sun exposure during the summer without compromising social life and consequently global quality of life. This seems to be particularly true mainly in young adult patients and the problem seems to affect more females than males.

In particular the results of skin reflectance measurements (statistical analysis) demonstrate that Anthelios XL is capable of offering adequate protection against hyperpigmentation of unaffected skin in vitiligo patients. The difference was noted mainly on the back of the hands and not on the face. Clinical evaluation confirmed, at least in part, the instrumental results.

There might be two possible explanations for this finding: the different pattern of solar exposure between the hands and the face (hands may be exposed for longer periods and receive UV rays perpendicularly), and the possibility that patients do not apply the same quantity of product on the hands and on the face for cosmetic reasons.

The ability of a sunscreen to inhibit pigmentation in normal skin is certainly related to its broad spectrum absorption, to the SPF and to its protection against UVA. To be effective, the products with high SPF need to have a corresponding high protection factor for UVA. These may be the reasons for which Anthelios XL has proved to be significantly effective.

## CONCLUSIONS

The results of this clinical study indicate that Anthelios XL 60+ was very effective in preventing excessive tanning in patients affected with vitiligo that were exposed to a high level of solar radiation during the summer in the Mediterranean area. A higher efficacy was noticed on the hands of the patients as compared to the face.

On the basis of these results Anthelios XL 60+ can be recommended as a sunscreen of choice for patients with vitiligo that do not want to, or cannot, avoid solar exposure during summer in Mediterranean countries or other locations where solar irradiation is particularly intense.