

# Report on the Clinical, Unicentre Pilot Study of the Effects of 308-Nm Monochromatic Excimer Light (Excilite®) on Repigmentation in Patients Suffering from Vitiligo

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## MATERIALS AND METHODS

During the period from February to July 2004 a study was carried out on the effects of 308-nm monochromatic excimer light (EXCILITE® - DEKA) on repigmentation in patients suffering from vitiligo. The study was carried out in the Dermatological Department of the Hospital de la Santa Creu i Sant Pau. A total of 10 patients were enrolled, 8 of whom were women and 2 men.

All the patients treated complied with the inclusion criteria and were ascertained as suitable for following the period and rhythm of the treatment stipulated. The patients all had localised plaques of multiple vitiligo which did not affect more than 20% of their body surface. Informed consent was obtained from all the patients and in all cases a phototype test was carried out on the normal pigmented skin of their backs prior to beginning the treatment.

The patients were treated twice a week on alternate days over a period of 4 months, with a maximum of 34 sessions.

The initial fluence used for each patient was 70% of the MED with a progressive increase during the following treatments, depending on the clinical response of the patient, up to maximum doses of 2.1-2.2 J/cm<sup>2</sup> in compliance with the patient's phototype. The dose was kept constant even when minimum signs of erythema were observed. In the case of patients presenting symptomatic erythema or the onset of blistering, the treatment was not carried out in the symptomatic area.

Wherever the area irradiated was the face, special glasses were worn for protecting the eyes from the UV rays. In the case of the vitiligo affecting the eyelids or the orbital area,

the patients were asked to close their eyes during treatment.

The skin not affected by vitiligo was protected with a sunscreen before the treatment in order to avoid any unnecessary exposure or secondary hyper-pigmentation.

As a complementary treatment, Polypodium leucotomus (Difur®) was indicated due to its known immunomodulating effects before ultraviolet radiation. Nine patients with symmetrical lesions on both sides were indicated for the application of topical tacrolimus on the right side of the body to ascertain whether there were any significant differences between the degree of repigmentation on this side and the symmetrical lesions on the left side.

## PATIENTS

All the patients were examined in the dermatological department of the Hospital de la Santa Creu i Sant Pau, Barcelona, Spain. The patients were classified according to their phototype, evolution of the disease, location of the lesions, and history of previous treatments.

The exclusion criteria were: treatment with phototherapy or PUVA during the three previous months, age < 15 years, phototypes I or II, and pregnant women. Unlike the other studies, patients with active vitiligo were included in order to demonstrate the effectiveness of the treatment during this phase of the disease; likewise patients with a widespread evolution of the disease were also included. A total of 10 patients were studied (8 women, 2 men) with a mean age of 33 years. The vitiligo was found in the active phase in 7 cases and in the stable phase in 3 cases. The disease had an evolution ranging from between

5 to 32 years with a mean of 13 years. The characteristics of the patients are illustrated in the annexed table.

One patient had acrofacial vitiligo and the remaining 9 had generalised forms affecting less than 20% of the body surfaces. Seven patients were phototype III and 3 patients were phototype IV.

Digital photographs were taken with a traditional numeric camera, Olympus 5050 brand and photos were also taken with a UV light using a UV-DA device (Clearstone, Mediform, Barcelona, E). An Olympus 5050 camera flash was used to activate the two flashes with UVA light. The lesions were photographed before starting the therapy, during the 15<sup>th</sup> session, and at the end of the treatment.

## **ASSESSMENT OF THE EFFECTIVENESS OF THE TREATMENT**

The repigmentation was classified in accordance with the percentage of repigmentation observed in the area treated. The assessment was carried out by three independent observers who compared the results of the normal photographs with the corresponding images in the ultraviolet images.

The areas treated were assessed in a separate manner and the response to the treatment was classified as “no repigmentation” (grade 0), “scarce repigmentation” (between 1% and 25%), “moderate repigmentation” (grade 2, between 26% and 50%), “good repigmentation” (grade 3, between 51% and 75%) and “excellent repigmentation” (grade 4, over 75%).

## **RESULTS**

Seven out of the ten patients included in the study were able to complete the 4 month's treatment. Three patients only took part in half of the sessions scheduled due to work problems.

Nine patients obtained some degree of repigmentation (90%). Three out of the seven patients who completed the study (42.85%) achieved moderate repigmentation and 2

(28.57%) showed excellent repigmentation. Only in one case was there a progression of the activity of the disease without achieving repigmentation in any of the areas treated.

80% of the patients began the repigmentation during the first 12 sessions of treatment.

There were differences in the degrees of repigmentation obtained depending on the body area treated. The results of the different areas are illustrated in the annexed table.

The best response was obtained in the lesions located on the face. There was also good repigmentation on the extremities (arms, elbows and legs) in the cases of phototype IV. The repigmentation of the lesions on the hands was scarce, and in the majority of cases insignificant. The accumulated doses of UVB ranged between 14.77 and 58.82 J/cm<sup>2</sup> (mean 39.28 J/cm<sup>2</sup>) with an average mean dose of 1.32 J/cm<sup>2</sup>.

The side effects observed included symptomatic erythema in five patients and one case of labial herpes in which the mouth area was treated.

Four out of the seven patients who completed the study showed differences between the side treated with topical tacrolimus + Excilite (right side) vs. Excilite by itself (left side). This difference showed a 50% improvement in 2 cases, and a 25-30% improvement in the other 2 cases. One patient reported having noticed that the area treated with tacrolimus was repigmented earlier than the other one, however at the end of the treatment no significant differences were observed between the two sides. One interesting fact was that on evaluating the patient's expectations with respect to the treatment with the tacrolimus cream, 6 out of the 9 patients treated insisted that they noticed a better repigmentation on the side treated with tacrolimus, with improvements reaching 80% in one case.

To sum up, it is necessary to point out how in the group of 7 patients who suffered from vitiligo in the active phase, only in one case did the disease continue to progress. In all the remaining 6 cases not only did the process stop, but accepted repigmentation results were also achieved.

**ANNEXED TABLE:**

<i>Patient</i>	<i>Age</i>	<i>Phototype</i>	<i>Years of Evolution</i>	<i>Phase of Vitiligo</i>	<i>Areas Treated</i>	<i>No. Sessions</i>	<i>Score Repigmentation</i>
1	26	III	7	Active	Face Armpits Forearm Breasts Thighs	34	0 0 0 0 0
2	31	III	10	Stable	Face	14	2
3	33	IV	4	Active	Face Elbows Hands	34	4 3 0
4	35	III	32	Active	Face Back of neck Armpits Intermammary area	33	3 1 2 1
5	42	III	2	Active	Forehead Back Neckline Armpits	34	2 1 1 2
6	16	IV	8	Stable	Mouth area Knees Elbows	33	4 4 4
7	67	III	25	Active	Mouth area Hands Forearms Wrists Elbows	34	4 1 4 1 2
8	27	IV	18	Active	Eyelids Knees Elbows	25	4 2 2
9	22	III	5	Active	Face Hands Elbows Armpits	19	1 2 1 1

Male Knee  
Fitzpatrick Skin Type III  
Intensity: 50mW/cm<sup>2</sup>

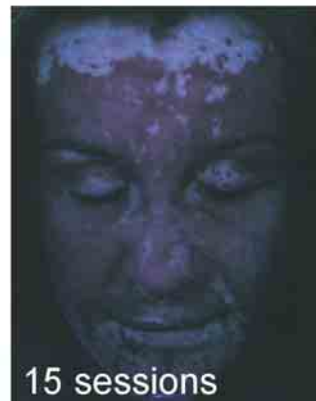


Female Face

Fitzpatrick

Skin Type III

Intensity: 50mW/cm<sup>2</sup>



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