

Double Blind, Placebo Controlled Evaluation of a Novel Skin Lightening Agent

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ABSTRACT

Melasma remains a troubling problem for physicans and patients alike. It is a chronic irregular, symmetric hyperpigmentation seen most often in women. In this study, a unique combination of ingredients with non-irritating properties was tested for treatment of melasma. In a double blind, placebo controlled, split face trial, 17 patients with melasma were treated on one half of the face, left or right, while the other received placebo control. All patients used sunscreen on both sides. Measurement with a colorimeter (Mexameter) was taken at baseline and after 8 weeks of daily use. The active side showed an objective decrease in hyperpigmentation of 14.60% while the control side showed a decrease of 9.82%. We conclude the product provides a non-irritating effective therapy for melasma.

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INTRODUCTION

Melasma is a chronic, often refractory disorder characterized by irregular patches of hyperpigmentation in a symmetric distribution on the sun exposed area of the face. It is most often seen in women, skin types III-V, but it can be seen in other skin types and in men as well. The pathogenesis is not well understood, but it is associated with UV light stimulating hyperactive melanocytes as well as female sex hormones. Treatment is often unsatisfactory due to frequent recurrence. The mainstay of therapy has been skin lightening creams containing hydroquinone, which act by blocking tyrosinase in the production of melanin. The most effective formulation seems to be a triple combination of hydroquinone, tretinoin, and a steroid to enhance tolerability. Other topicals include kojic acid, azelic acid, ascorbic acid, retinoids, phloretin, ferulic acid, lignin peroxidase.[1] These products are typically utilized in a program of sunscreen and sun protection to minimize UV exposure. Further treatments include chemical peels with glycolic acid, salicylic acid, and trichloroacetic acid. Finally, laser and light devices can be used with caution to target pigment, but post-inflammatory hyperpigmentation is common in melasma patients.[1]

Hydroquinone is irritating and, although highly unlikely, the FDA has raised the specter of carcinogenesis with this product, and therefore a search for an alternative has been pursued. This has led to a host of botanical products being introduced to the market containing ingredients such as Silymarin, arbutin, resveratrol, aloe vera, pycnogenol, bosweillia, aloesin, nicinamide, and extracts of coffeeberry, soy, green tea, orchids, grape seed, marine algae, and licorice to name a few.[2]

LumaPro-C is a unique blend of ingredients meant to address the need for safe and effective skin lightening for melasma as well as general skin brightening. It is thought to work by three mechanisms. First, it contains a resurfacing peptide with stabilized vitamin C to promote exfoliation. Second, it contains botanicals to reduce melanogenisis and inflammation including resveratrol, daisy and pine extracts, and ginger extract. Finally, to further impede melanogenisis an encapsulated plankton extract and a probiotic regulator are included. It was our intention to test this product's ability to reduce the hyperpigmentation of melasma.

METHODS

Seventeen patients, all women with facial melasma, were recruited for this study. At baseline, a mexameter, which is a type of colorimeter that objectively measures brown and red, was used to take readings from the worst involved areas on both sides of the face. Patients were instructed to use sunscreen on both sides of the face twice daily and given samples to do so. Patients were then randomized to receive active cream or placebo, each to be applied to one side of the face left or right BID for 8 weeks. Patients and the evaluating physician were blinded as to which side was active and which was control. Patients were photographed and mexameter readings taken at baseline, at 2 weeks, 4 weeks, and 8 weeks. At the end of the study, patients were asked to evaluate if they could perceive one side to look better than the other, and a physician's global assessment asked the same question.

RESULTS

Sixteen of the seventeen patients enrolled completed the 8-week study. At the end of 8 weeks, the control side showed an average decreased mexameter reading of 9.82%, while the active side showed an average decrease of 14.60% (Table 1). On the patient's subjective analysis, 13 of 16 patients reported they could

TABLE 1.

Mexameter Scores Showing Brown Pigmentation at Baseline and After 8 Weeks of Therapy

Patient	Mexameter Baseline		Mexameter 8 Weeks		Percent Change
1	active	200	active	174	13.00%
	Control	180	control	199	-10.60%
2	active	259	active	209	19.30%
	Control	274	control	263	4.00%
3	active	217	active	216	0.50%
	Control	210	control	234	-11.40%
4	active	188	active	159	15.30%
	Control	197	control	165	17.20%
5	acçive	181	active	134	26.00%
	Control	181	control	164	11.40%
6	active	199	active	173	13.10%
	Control	193	control	161	11.40%
7	active	116	active	91	21.60%
	Control	168	control	115	31.50%
8	active	198	active	170	14.10%
	Control	214	control	203	5.10%
9	active	280	active	214	33.30%
	Control	264	control	239	9.50%
10	active	152	active	150	1.32%
	Control	185	control	162	12.40%
11	lost to follow up				
12	active	249	active	213	14.50%
	Control	256	control	222	13.30%
13	active	156	active	158	-1.28%
	Control	285	control	230	19.30%
14	active	179	active	182	-1.68
	Control	211	control	203	4.70%
15	active	158	active	107	32.30%
	Control	171	control	118	31.00%
16	active	222	active	131	41.00%
	Control	253	control	177	30.00%
17	active	189	active	172	9.00%
	Control	199	control	177	11.10%

notice one side was better than the other (Figure 1). On the physician's assessment, 12 of 16 patients were noticed to have one side have better appearance with less hyperpigmentation. The better side was always the active cream side. On the physician's assessment, it was also noted several patients appeared to have brighter non-hyperpigmented skin on the treated side (Figure 2).

FIGURE 1. Left side at baseline.

FIGURE 2. Same patient at week 8.

DISCUSSION

Melasma remains a frustrating condition for patients and physicians alike. LumaPro-C seems to provide significant improvement in the hyperpigmentation of melasma with no significant irritation reported. It provides an alternative to conventional therapy to those seeking a non-irritating gentle treatment. Additionally, LumaPro-C can provide an effective solution for maintaining results during necessary breaks from the use of more aggressive skin lighteners such as hydroquinone. Individuals prone to melasma are seeking solutions that will help them achieve an even skin tone without the risk of recurrence. This requires addressing existing pigmentation while also preventing future pigmentation. LumaPro-C was developed to address less severe incidences of hyperpigmentation by gently resurfacing skin. Additionally, it provides effective actives to brighten skin and reduce the manifestation of irregular discoloration caused by melanocyte hyperactivity.

DISCLOSURES

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