

# Melano Corrective System vs. Obagi® Nu Derm for Hyperpigmentation

## Clinical Assessment Results

### INTRODUCTION

Due to the high irritation rates, photosensitivity and atrophy of the skin, many of the current therapy options for hyperpigmentation require a patient to stop use of the treatment product for a period of time. There is then a relatively high risk of recurrence of the hyperpigmentation during this time period. Patients are often unhappy with the negative side effects in conjunction with the resolution results of their treatment regimen. The Epionce® Melano Corrective System (MCS), which includes the MelanoLyteTx™ and MelanoLyte™ PRO, was developed to help solve the problems of current regimens.

The current gold standard for hyperpigmentation is prescription 4% hydroquinone (HQ) combined with tretinoin (TR) 0.05%. Ascorbic acid, corticosteroids, exfoliants or herbal extracts are added to the above to improve efficacy and tolerance of the prescription products. One of the most popular is the Obagi® Nu Derm System (OND), which is a complex multi-stage regimen containing all of the above, except corticosteroids.

MCS contains a unique blend of synergistic active ingredients, each of which individually has been found to improve the appearance of hyperpigmentation of human skin in in vivo trials. Moreover, each has been compared to and shown to have superiority to the most commonly used actives. Neither product contains hydroquinone, tretinoin, ascorbic or glycolic acid, soy, tea, kojic acid or niacinamide. Each of the actives in the MCS has a different mechanism of action, thus all contribute to expected improved efficacy and safety.

In a dermatologist-assessed controlled clinical trial, the concept behind the Melano Corrective System was validated. The study was conducted during the winter in Colorado to maximally stress the skin for risk of reactions to the product and rebound post-inflammatory hyperpigmentation (PIH).

### METHOD

Two Epionce regimens were compared with Obagi Nu Derm System, consisting of prescription tretinoin 0.05% and hydroquinone 4% in an 18-week prospective, parallel, controlled clinical trial during the fall and winter months. The 56 panelists were randomized into three cells. 19 were treated with the full MCS, 19 were treated with only the MelanoLyte Tx, and 18 were treated with OND. Three racial groups - Caucasian, Hispanic, Asian - were included with mild to severe hyperpigmentation. Assessments were performed by expert investigators at 0, 4, 8, 12 and 18 weeks for both safety and efficacy. A 6 week regression period occurred between weeks 12 and 18. During this time period, all three cells discontinued use of the treatment products to determine rebound effect and continued irritation reactions.

The regimen for Cell 1 consisted of Epionce Gentle Foaming Cleanser, MelanoLyte Tx and Renewal Facial Lotion applied twice daily with Ultra Shield Lotion SPF 50 applied only in the morning. Once a week, the panelists applied the MelanoLyte PRO treatment mask in the evening. The regimen for Obagi Nu Derm System, Cell 2, consisted of Foaming Cleanser, Toner, Clear, Exfoderm, Blender, Physical UV Block SPF 32

(AM only). Clear and Blender contain prescription 4% hydroquinone and prescription tretinoin 0.05% is added to the Blender. The regimen for Cell 3 consisted of Epionce Gentle Foaming Cleanser, MelanoLyte Tx and Renewal Facial Lotion applied twice daily with Ultra Shield Lotion SPF 50 applied only in the morning. The MelanoLyte PRO was not used by Cell 3. All regimens for each Cell occurred for the initial 12 weeks.

During the 6 week regression period, Cell 1 stopped using both the MelanoLyte Tx and the MelanoLyte PRO, Cell 2 stopped using the Clear and Blender products and Cell 3 stopped using the MelanoLyte Tx.

### RESULTS

Table 1 shows the safety results from this study against baseline. As seen in Table 1, Cells 1 and 3 had excellent safety data. However, by week 4, the Cell 2 panelist regimens had to be modified due to intolerable contact reactions. Not one panelist in Cell 1 or 3 had to make such adjustments. Additionally, Table 1 shows that after 12 weeks, Cell 2 had increased erythema by 66.6% and scaling/dryness by 200%. Additionally, it induced peeling in 44.4% at week 4, and 27.7% at week 12. At week 18, 6 weeks following the completion of treatment, Cell 2 panelists continued to suffer from symptoms that included a 53.3% increase in erythema over baseline, however, scaling/dryness improved 66.6% over baseline. In conclusion, Cell 1 and 3 were highly statistically superior ( $p < 0.001$ ) in safety to Cell 2.

Table 2 shows the efficacy results from this study against baseline. Four types of hyperpigmentation were evaluated including lentigines (freckling), mottled hyperpigmentation, hormonal (melasma) and dyschromia. Cell 1 was statistically significant ( $p < 0.05$ ) to Cell 2 in relieving mottled hyperpigmentation on the whole face and cheeks at 18 weeks. Cell 1 also showed a statistically significant improvement in lentigines at 8, 12 and 18 weeks, while the lentigines for Cell 2 panelists rebounded to become worse than baseline by week 18 (+31.2%). Total facial and forehead dyschromia had comparable resolution of hyperpigmentation at all time points with all three Cells. For melasma, Cell 1 had a statistically significant reduction (19.3%) on the forehead and Cell 3 had a statistically significant reduction (19.1%) on the cheeks, over Cell 2 which showed a reduction of 10.5% and 12.7%, respectively at 4 weeks. Chin melasma showed a trend toward statistical significance ( $p < 0.10$ ) of Cell 1 over Cell 2 at both the 12 and 18 week time points. As seen in Table 2, Cell 1 was shown to reduce chin melasma by 57.8% at 12 weeks, compared to 26.8% improvement for Cell 2. At 18 weeks, Cell 1 panelists had a 29.6% reduction in chin melasma compared to 12.1% in Cell 2.

### DISCUSSION

Epionce Melano Corrective System appears to be the first non-prescription system to directly compare itself to the Obagi Nu Derm system - the prescription gold standard for treating visible signs of hyperpigmentation. The MCS regimen is shown to be comparable in efficacy, but is overall profoundly safer. The increase in safety should allow for regular use of the MCS, providing continued resolution of visible hyperpigmentation over the long-term.

**Melano Corrective System vs. Obagi Nu Derm for Hyperpigmentation, cont.**

**Table 1 - Safety (Data vs. Baseline)**

Parameters	Cell 1				Cell 2				Cell 3			
	4 weeks	8 weeks	12 weeks	18 weeks	4 weeks	8 weeks	12 weeks	18 weeks	4 weeks	8 weeks	12 weeks	18 weeks
Erythema	+10.5 NS	+5.2 NS	+21.0 NS	+26.3 T	+93.3 SS	+100.0 SS	+66.6 SS	+53.6 SS	9.5 NS	30.4 SS	4.3 NS	8.6 NS
Scaling/Dryness	100.0 SS	100.0 SS	100.0 SS	100.0 SS	+66.6 SS	+116.6 SS	+200 SS	66.6 SS	0	0	0	0
Dry/Tight	81.8 SS	90.9 SS	100.0 SS	90.9 SS	+89.4 SS	47.3 SS	10.5 NS	78.9 SS	88.8 SS	100.0 SS	90.0 SS	90.0 SS
Itching	100.0 SS	100.0 SS	100.0 SS	100.0 SS	0	0	0	0	0	0	0	0
Burning/Stinging	0	0	0	0	+22.2 NS	0	+5.5 NS	0	0	0	+5.5 NS	0
Peeling	0	0	0	0	+44.4 SS	0	+27.7 T	0	0	0	0	0

**Table 2 - Efficacy (Data vs. Baseline)**

Parameters	Cell 1				Cell 2				Cell 3			
	4 weeks	8 weeks	12 weeks	18 weeks	4 weeks	8 weeks	12 weeks	18 weeks	4 weeks	8 weeks	12 weeks	18 weeks
<b>Lentiginos/Freckling</b>												
Whole face	7.7 NS	22.0 SS	37.6 SS	27.2 SS	6.2 NS	25.0 SS	37.5 SS	+31.2 SS	0	0	0	0
Cheeks	8.3 NS	26.0 SS	41.6 SS	34.7 SS	0 NS	16.6 SS	33.3 SS	+100.0 SS	0	0	0	0
<b>Melasma</b>												
Whole face	10.1 SS	30.3 SS	43.6 SS	30.3 SS	11.8 SS	29.6 SS	36.7 NS	27.0 SS	12.5 SS	28.9 SS	37.1 SS	30.8 SS
Cheeks	10.8 SS	36.9 SS	58.6 HS	50.0 SS	12.7 SS	31.7 SS	36.3 SS	36.3 SS	19.1 SS	29.7 SS	36.1 SS	29.7 SS
Chin	3.7 NS	44.4 SS	57.8 SS	29.6 SS	12.1 SS	24.3 SS	26.8 SS	12.1 SS	6.5 NS	23.9 SS	32.6 SS	28.2 SS
Forehead	19.3 SS	25.8 SS	38.7 SS	22.5 SS	10.5 T	37.5 SS	50.0 HS	39.4 SS	6.8 NS	37.9 SS	48.2 HS	41.3 SS
<b>Mottled Hyperpigmentation</b>												
Whole face	10.6 SS	22.7 SS	30.3 SS	17.8 SS	12.4 SS	30.6 SS	39.2 SS	26.1 SS	10.1 SS	22.1 SS	26.9 SS	17.3 SS
Chin	20.0 SS	46.6 HS	53.3 HS	46.6 SS	30.0 SS	56.2 HS	60.0 HS	50.0 HS	15.0 SS	40.0 SS	40.0 SS	25.0 SS
<b>Dyschromia</b>												
Whole face	10.2 SS	29.4 SS	37.5 HS	21.3 SS	13.8 SS	31.7 SS	38.6 HS	24.8 SS	13.6 SS	29.7 SS	37.4 HS	23.6 SS

For Tables 1 and 2

SS (Statistically significant  $p < 0.05$ ); NS (Not statistically significant  $p > 0.10$ ); T (Trend towards statistical significance  $p < 0.10 - p < 0.05$ )

HS (Highly statistically significant  $p < 0.001$ ); + (indicates a worsening of the parameter); No + (indicates an improvement of the parameter)

o (indicates panelists did not exhibit the parameter)