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Treating Photodamage of the Décolletage Area With a Novel Copper Zinc Malonate Complex Plus Hydroquinone and Tretinoin

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ABSTRACT

There has been a proliferation of treatments for facial rejuvenation but, curiously, the use of such treatments on other areas of the body has not been widely investigated. The clinical effects of treating photodamaged skin of the neck and anterior chest area (décolletage) with a proprietary copper zinc malonate lotion and a proprietary 4% hydroquinone cream (twice daily), plus tretinoin cream (once daily), were evaluated in 42 females in a 24-week investigator-blind randomized study.

Treatment was associated with early and significant ($P \leq 0.05$) improvements in mean scores on an overall integrated assessment of photodamage (from week 4 onward) and for multiple signs of photodamage—tactile roughness (from week 2 onward); mottled hyperpigmentation, lentigines and fine wrinkling (from week 4 onward); laxity (from week 8 onward); and crepiness and coarse wrinkling (from week 12 onward). Treatment was generally well tolerated and 94% of subjects were satisfied or very satisfied with the overall improvement in their décolletage at week 24.

INTRODUCTION

Although there has been a proliferation of facial rejuvenation treatments in recent years, such treatments have not been widely evaluated in areas of the body other than the face. The décolletage (the neck and anterior chest) may also benefit from treatment. The skin in this area is exposed to ultraviolet light (UV) and individuals may not apply sunscreen as frequently as on the face, rendering the area susceptible to photodamage. Treatment of photodamage in the décolletage area is also useful when performed in conjunction with facial rejuvenation as it helps to avoid a visible line of demarcation between a rejuvenated face and a relatively aged neck.[1–3]

Previous studies relating to treatment of the décolletage area focus on the neck and often describe physician-administered treatments such as surgery[4–6] or injections of botulinum toxin type A.[7–9] However, in addition to being invasive, such procedures tend to offer improvements only in particular aspects of photodamage—for example, both these treatments offer improvements in wrinkling but not in dyspigmentation.

Non-invasive methods of contracting tissue include non-ablative radiofrequency treatment,[10,11] laser treatment,[12] and infra red light treatment.[13,14] Non-ablative treatments generally improve skin texture and tone, with some also improving wrinkles and some improving dyspigmentation.[15] Although the majority of studies focus on the treatment of facial skin, a few have evaluated such treatments on the neck or chest. For example, non-ablative radiofrequency has been reported to achieve significant improvements in the laxity of neck skin in the majority of treated patients.[11] However, Ruiz reports that treatment of the lateral aspects of the neck can be exquisitely painful and associated with a higher than average risk of complications.[10] Instead, he suggests that improvements in neck laxity be achieved by treating just key areas or "anchoring points". In a study of 20 patients, treatment with a non-ablative 1540 nm Er:glass laser has been reported to significantly increase dermal thickness in the neck.[12] The patients were very satisfied by the improvement in their skin tone and moderately satisfied by the improvement in their skin texture. In addition, all 20 of the patients were extremely satisfied overall and no adverse effects were reported. Infrared light treatment of the neck in the submental area has also been reported to be very well tolerated.[13] Infrared light treatment of the lower neck and face has been reported to achieve a significant improvement in the tightness of the skin in all 19 patients evaluated in one study.[14]

Another treatment modality which is widely used to improve the appearance of skin is intense pulsed light therapy. Such treatment has been shown to be effective in reducing hyperpigmentation associated with poikiloderma of Civatte on the neck and chest, and can also improve skin texture.[16–18] It is reported to be generally well tolerated in these areas.

In common with the non-ablative rejuvenation treatments, medical therapies (including topical retinoids, alpha hydroxy acids, and vitamin C) have primarily been studied on the face with little attention paid to the décolletage area.

In this study, the authors evaluated a system which involves applying a proprietary copper zinc malonate lotion and a 4% hydroqui-

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none cream, in conjunction with topical tretinoin. Previous studies have indicated that the copper zinc malonate lotion can enhance elasticity and reduce wrinkling independently of any moisturization effect, as well as increase the levels of collagen.[19] Histologically, there is evidence of elastic fiber regeneration, enhanced biosynthesis of elastin, and the replacement of clumped and relatively thick elastic fibers by finer and more discrete fibers.[20] The second component of the system—the hydroquinone cream—is useful in treating hyperpigmentation.[21] In addition, tretinoin cream can ameliorate both wrinkling and dyspigmentation.[22]

METHODS

Subjects

Subjects were eligible to enroll in this single-center, randomized, parallel-group study if they were 40–60 years of age (inclusive) and their décolletage showed at least moderate levels of photodamage on an overall integrated assessment and at least moderate levels of mottled hyperpigmentation, fine wrinkling or coarse wrinkling. Moderate levels of these parameters were signified by a score of at least 3 on a 6-point scale where 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe and 5=very severe. Subjects were also required to be willing to refrain from using any non-study moisturizers, sunscreens, make-up, and topical self-tanning products on their décolletage during the study, and to avoid excessive sun exposure and the use of tanning booths.

Exclusion criteria included: hypersensitivity to any ingredient in the study products; concurrent use of other medicated products on the décolletage; application of a moisturizer on the décolletage in the 24 hours preceding the baseline visit; use of a systemic retinoid or application of a topical retinoid on the décolletage in the preceding six months; and treatment with a medical procedure (e.g., chemical peel, laser resurfacing, or plastic surgery) on the décolletage in the preceding 12 months.

Treatment Regimen

All subjects were instructed to apply the proprietary zinc copper malonate lotion (ELASTIderm™ Décolletage Wrinkle Reducing Lotion, Obagi Medical Products, Inc. [OMP], Long Beach, CA) and a proprietary formulation of 4% hydroquinone cream (ELASTIderm Décolletage Skin Lightening Complex, OMP) to their entire décolletage each morning and evening for 24 weeks.[1] Together, both products are known as the ELASTIderm Décolletage System (OMP, Inc.). They were randomly assigned to also apply either 0.025% tretinoin cream or 0.05% tretinoin cream once daily, in the evening. The two strengths of tretinoin were used because retinoid irritation on the chest was a significant possibility in view of the extensive photodamage in this group of patients

Subjects were instructed to apply a dime-sized amount of the hydroquinone cream first, either alone (in the case of the morning application) or pre-mixed in the palm of their hand with a dime-sized amount of tretinoin cream (in the case of the evening application). After this, two pumps of the zinc copper malonate lotion were to be applied. For the first three weeks, weekday morning applications of the study products were performed under supervision at the study center; thereafter, and for all evening and weekend applications, applications were unsupervised although written and verbal instructions were provided by clinical site staff.

Subjects were allowed to use their normal body cleansing products and were instructed not to wash for at least four hours after applying the test agents. The use of a specified moisturizer containing 20% glycerin and 1% dimethicone (CLENZIderm MD™ Therapeutic Moisturizer, OMP) was allowed as needed. At the investigator's discretion, subjects in the 0.05% tretinoin group were allowed to switch to using 0.025% tretinoin for the remainder of the study if they experienced tolerability issues.

Outcome Measures

Efficacy was evaluated every four weeks in terms of an overall integrated assessment of décolletage photodamage and also in terms of tactile roughness, mottled hyperpigmentation, lentigines, fine wrinkling, laxity, crepiness (a wrinkled appearance similar to crepe paper) and coarse wrinkling using the 6-point scale described above.

Subjects were asked to rate their satisfaction with the overall improvement in their décolletage using a scale of very satisfied, satisfied, indifferent, somewhat dissatisfied and not at all satisfied.

The irritation potential of the treatment was assessed in terms of erythema, dryness, peeling and burning/stinging (Table 1). During the first three weeks these were reported every weekday by a masked expert grader. They were also reported every four weeks by the investigator. Each parameter was evaluated immediately before the next application of study products and, for the burning/stinging evaluations, the masked grader or investigator asked the subject for their rating.

Statistical Analyses

Analyses were performed using a *t* test (for between-group differences in age), the Wilcoxon rank sum test (for between-group differences in Fitzpatrick skin type, efficacy scores and tolerability scores), and the Wilcoxon signed rank test (for within-group differences in efficacy scores from baseline). A *P* value of ≤ 0.05 was considered statistically significant.

RESULTS

Subjects

A total of 42 females were enrolled (21 in each group), of whom 38 (91%) completed. The majority of subjects had severe or very severe photodamage on their décolletage with large areas of melanocytic hyperplasia (solar lentigines) (Figure 1). In addition, all subjects had moderate or severe wrinkling.

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The mean age of the subjects was 50 years and all were white with Fitzpatrick skin types of III (38%) or IV (62%). There were no significant between-group differences in age or Fitzpatrick skin type.

Efficacy

Mean scores for the overall integrated assessment of the décolletage area were significantly reduced from baseline in both groups from week 4 onward ($P \leq 0.05$; Figures 2 and 3). In the group treated with the décolletage system plus 0.025% tretinoin, the proportion of subjects who achieved at least a 2-point improvement in their overall integrated assessment score (e.g., from severe to mild, or moderate to minimal) increased from 15% at week 8 to 25% at week 16 and to 35% at week 24. The corresponding data in the group treated with the décolletage system plus 0.05% tretinoin showed higher proportions at each of these time points—increasing from 25% at week 8 to 33% at week 16 and to 39% at week 24. However, these values were not significantly different from those in the other group. The proportion of subjects achieving at least a 2-point improvement was still increasing at the end of the study.

As with the overall integrated assessment, mean scores for each of the other investigator-assessed efficacy outcome measures were also significantly reduced from baseline in both groups ($P \leq 0.05$)—from week 2 onward for tactile roughness; from week 4 onward for mottled hyperpigmentation, lentigines, and fine wrinkling; from week 8 onward for laxity; and from week 12 onward for crepiness and coarse wrinkling (Table 2). There were no significant between-group differences for any of these eight parameters, except that crepiness at week 8 was significantly less severe in the group using 0.025% tretinoin than in the group using 0.05% tretinoin (Table 2).

Across both groups at week 4, the proportion of subjects showing at least a 1-point improvement in mottled hyperpigmentation or fine wrinkling (e.g., from severe to moderate, or from moderate to mild) was 73% and 78%, respectively (Table 3). At week 24, the proportion of subjects showing at least a 2-point improvement in mottled hyperpigmentation or fine wrinkling (e.g., from severe to mild, or moderate to minimal) was 61% and 42%, respectively (Table 3).

Across both groups, the percentage of subjects who had no more than minimal levels of mottled hyperpigmentation increased from 0% at baseline to 13% at week 4 and 79% at week 24. Similarly, the percentage of subjects with no more than mild levels of fine wrinkling increased from 0% at baseline to 53% at week 4 and 100% at week 24.

FIGURE 1. Typical baseline severity of photodamage in the décolletage area.

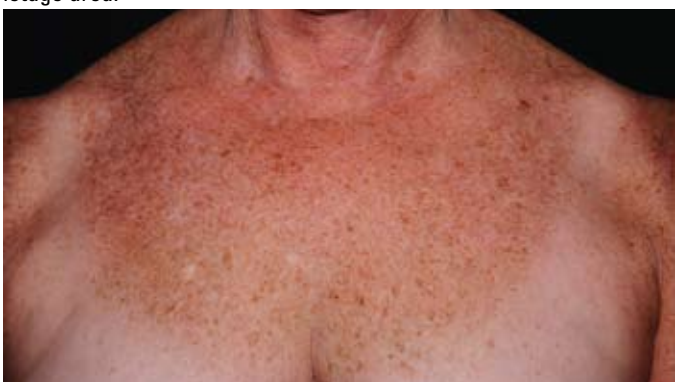
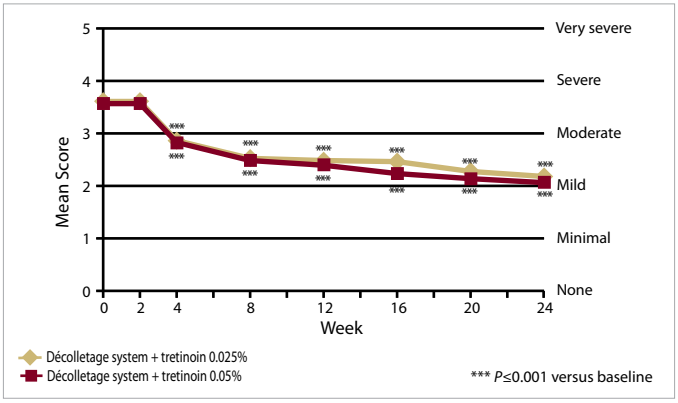


FIGURE 2. Mean scores for the overall integrated assessment of photodamage in the décolletage area.



Subject Satisfaction

Overall, the proportion of subjects who were satisfied or very satisfied with the overall improvement in their décolletage was 44% at week 2, 83% at week 4, and 94% at week 24 (Figure 4).

TABLE 1.

Scales Used to Assess Tolerability

Scale	Erythema	Dryness	Peeling	Burning/ Stinging
0	None–no erythema present	None	None	None
1, 2 or 3	Mild erythema	Slight flaking	Mild–slight peeling	Barely perceivable to slightly perceivable
4, 5 or 6	Moderate confluent erythema to marked erythema, slight edema	Moderate flaking/ scaling to marked scaling, slight fissuring	Moderate–definitely noticeable peeling	Moderate
7, 8 or 9	Marked erythema, edema, flare, possible erosion	Severe scaling, fissuring	Severe–extensive peeling	Severe

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Tolerability

One (2%) subject, in the tretinoin 0.05% group, withdrew due to adverse events (hives and erythema in the chest area that was probably related to treatment). In addition, three (7%) asked to withdraw for the following reasons: one subject was concerned that transient small erythematous patches, which were not considered a treatment-related adverse event and which fully resolved within one day, might recur (tretinoin 0.025% group); one subject considered treatment and visits were too time consuming (tretinoin 0.05% group); and one subject had difficulty traveling to appointments following an injury (tretinoin 0.05% group).

Expert grader evaluations during the first three weeks of the study showed that there were no significant between-group differences in mean scores or cumulative mean scores for erythema, dryness, peeling or burning/stinging at any time point. Each of these parameters showed transient slight increases in mean score, with maximum mean scores generally occurring between days 14 and 16. Nevertheless, these resolved with continued treatment and, in both groups, mean scores did not exceed 1.4 for erythema (i.e. mild), 0.5 for dryness (less than slight), 0.5 for peeling (less than mild) or 0.6 for burning/stinging (less than barely perceivable) (Table 4).

The number of subjects who interrupted treatment at some point due to treatment-related adverse events was six in the décolletage system plus tretinoin 0.025% group, and seven in the décolletage system plus tretinoin 0.05% group. In the décolletage plus tretinoin 0.025% group, the number of subjects who needed to use a moisturizer was one in the first week, three in the second week, and three in the third week. In the décolletage plus tretinoin 0.05% group, the number of subjects who needed to use a moisturizer was zero in the first week, four in the second week, and six in the third week.

TABLE 2.

Mean Scores (± SD) for Each Outcome Measure Evaluating a Specific Aspect of Photodamage

Parameter	Treatment Group	Week							
		Baseline	2	4	8	12	16	20	24
Tactile roughness	Décolletage system + tretinoin 0.025%	3.1 ± 0.59	2.7[a] ± 0.59	2.2[a] ± 0.49	1.7[a] ± 0.47	1.6[a] ± 0.60	1.4[a] ± 0.60	1.3[a] ± 0.47	1.2[a] ± 0.41
	Décolletage system + tretinoin 0.05%	3.2 ± 0.68	2.8[a] ± 0.77	2.3[a] ± 0.57	1.8[a] ± 0.41	1.5[a] ± 0.51	1.3[a] ± 0.49	1.3[a] ± 0.46	1.3[a] ± 0.46
Mottled hyperpigmentation	Décolletage system + tretinoin 0.025%	2.9 ± 0.85	2.9 ± 0.85	2.2[a] ± 0.67	1.9[a] ± 0.67	1.4[a] ± 0.59	1.2[a] ± 0.52	1.2[a] ± 0.52	1.2[a] ± 0.49
	Décolletage system + tretinoin 0.05%	3.1 ± 0.70	3.1 ± 0.72	2.2[a] ± 0.70	1.8[a] ± 0.64	1.5[a] ± 0.83	1.3[a] ± 0.75	1.2[a] ± 0.65	1.1[a] ± 0.58
Lentigines	Décolletage system + tretinoin 0.025%	3.4 ± 0.74	3.4 ± 0.75	2.9[a] ± 0.64	2.4[a] ± 0.88	2.2[a] ± 0.93	2.1[a] ± 0.97	2.1[a] ± 0.94	2.0[a] ± 1.00
	Décolletage system + tretinoin 0.05%	3.2 ± 0.81	3.2 ± 0.83	2.7[a] ± 0.88	2.2[a] ± 0.70	2.1[a] ± 0.69	1.9[a] ± 0.73	1.8[a] ± 0.79	1.6[a] ± 0.70
Fine wrinkling	Décolletage system + tretinoin 0.025%	3.3 ± 0.46	3.3 ± 0.44	2.4[a] ± 0.50	2.2[a] ± 0.41	2.0[a] ± 0.32	2.0[a] ± 0.32	1.9[a] ± 0.37	1.9[a] ± 0.37
	Décolletage system + tretinoin 0.05%	3.2 ± 0.44	3.2 ± 0.52	2.6[a] ± 0.51	2.3[a] ± 0.44	2.0[a] ± 0.22	1.9[a] ± 0.24	1.7[a] ± 0.46	1.7[a] ± 0.46
Laxity	Décolletage system + tretinoin 0.025%	2.9 ± 0.65	2.8 ± 0.62	2.6 ± 0.60	2.3[a] ± 0.57	2.1[a] ± 0.45	2.1[a] ± 0.45	2.1[a] ± 0.45	2.0[a] ± 0.60
	Décolletage system + tretinoin 0.05%	2.8 ± 0.70	2.8 ± 0.70	2.6 ± 0.69	2.5[a] ± 0.60	2.2[a] ± 0.41	2.1[a] ± 0.32	2.1[a] ± 0.32	2.1[a] ± 0.24
Crepiness*	Décolletage system + tretinoin 0.025%	2.5 ± 0.68	2.5 ± 0.69	2.2[a] ± 0.59	2.0[a,b] ± 0.46	1.9[a] ± 0.55	1.9[a] ± 0.55	1.8[a] ± 0.62	1.6[a] ± 0.68
	Décolletage system + tretinoin 0.05%	2.6 ± 0.74	2.7 ± 0.75	2.5 ± 0.69	2.4 ± 0.60	2.2[a] ± 0.52	2.1[a] ± 0.47	1.9[a] ± 0.58	1.6[a] ± 0.61
Coarse wrinkling	Décolletage system + tretinoin 0.025%	2.4 ± 0.87	2.4 ± 0.81	2.3 ± 0.73	2.2 ± 0.81	2.0[a] ± 0.60	2.0[a] ± 0.60	1.9[a] ± 0.64	1.9[a] ± 0.64
	Décolletage system + tretinoin 0.05%	2.3 ± 0.58	2.4 ± 0.59	2.3 ± 0.66	2.2 ± 0.52	2.0[a] ± 0.56	2.0[a] ± 0.59	1.8[a] ± 0.65	1.8[a] ± 0.65

[a] $P \leq 0.05$ compared with baseline.
[b] $P \leq 0.05$ compared with the group treated with the décolletage system + tretinoin 0.05%.
*Crepiness=a wrinkled appearance similar to crepe paper.

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Investigator evaluations of tolerability during the entire 24-week study period showed that mean levels of erythema, dryness, peeling and burning/stinging remained less than mild throughout the study with no significant differences between groups.

DISCUSSION

The results of this study show that use of the décolletage system in conjunction with tretinoin offers early and significant improvements in multiple signs of photodamage—tactile roughness (from week 2 onward), mottled hyperpigmentation, lentigines and fine wrinkling (from week 4 onward), laxity (from week 8 onward), and crepiness and coarse wrinkling (from week 12 onward). The proportion of subjects achieving at least a 2-point improvement in their score for the overall integrated assessment continued to increase during the last weeks of the study and may therefore have increased further still after the end of the 24-week study period. Importantly, a high proportion of subjects reported that they were satisfied or very satisfied with the overall improvement in their décolletage, with the proportion also increasing as the duration of treatment increased (44% at week 2, 83% at week 4 and 94% at week 24).

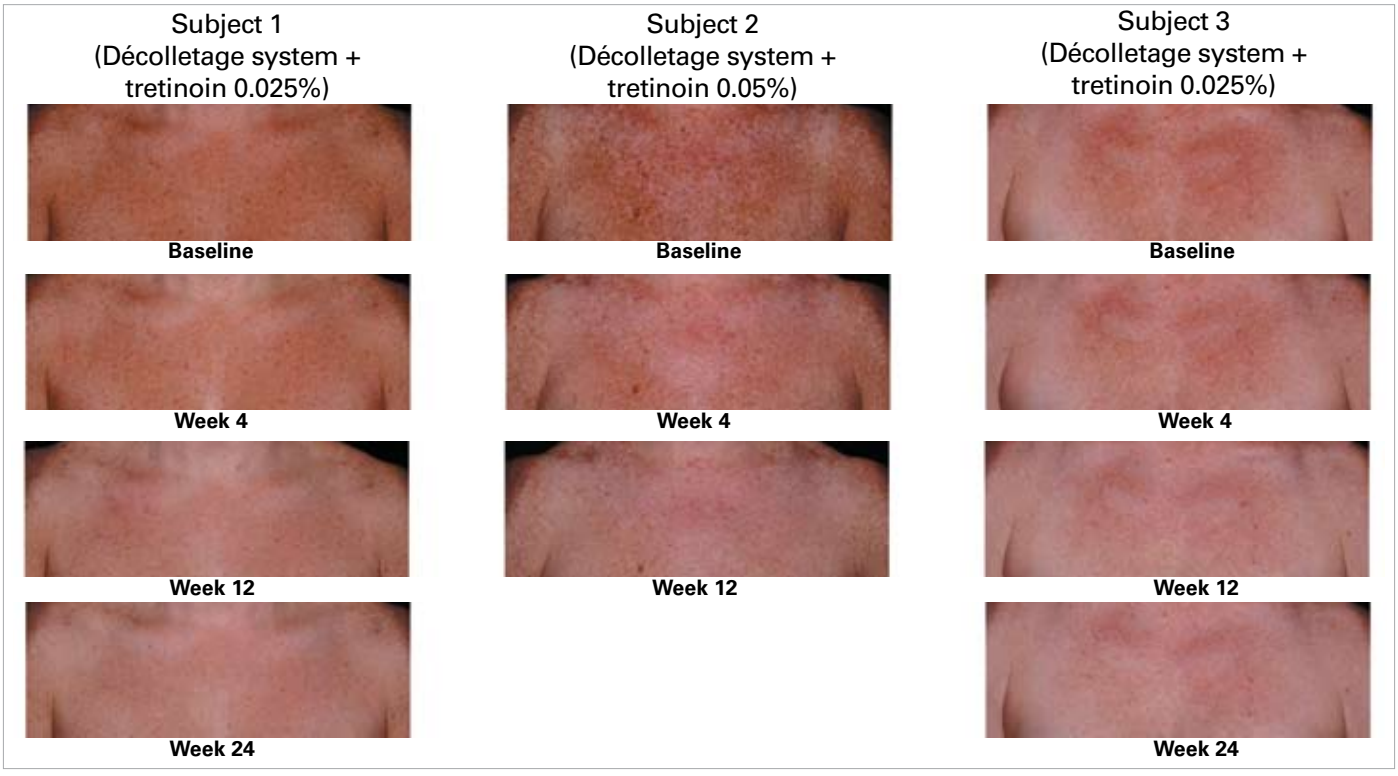
While the design of this study does not demonstrate the relative contribution for each component, tretinoin and hydroquinone are both FDA approved for treating hyperpigmentation and tretinoin is approved for treatment of skin wrinkling. A zinc copper malonate solution has been shown to reduce wrinkling in the periorbital region and to exert effects on the dermal matrix, particularly elastin fibers.[19,20] A much more involved study, in terms of number of patients randomized to individual components and the combined system, would be needed to make such a determination.

The system was generally well tolerated on the skin of the décolletage area regardless of which concentration of tretinoin cream was used (0.025% or 0.05%). Although some subjects experienced transient increases in erythema, dryness, peeling, and/or burning/stinging in the early weeks of treatment, this was transient and resolved with continued treatment. These signs and symptoms are unsurprising as they are commonly reported with the use of topical retinoids and/or hydroquinone. It is likely that both these agents contributed to the burning and stinging reported in susceptible subjects.

A copper zinc malonate formulation has been evaluated previously but only as a single agent on periorbital skin.[19,20] This is the first study evaluating its clinical benefits in the décolletage area and when used with hydroquinone and tretinoin.

As each of the three components of treatment evaluated in this study—copper zinc malonate complex, hydroquinone and tretinoin—is thought to have different and potentially complementary mechanisms of action, their use in combination may promote a better clinical outcome than that which might be

FIGURE 3. Clinical improvement in the décolletage visible within four weeks of treatment.



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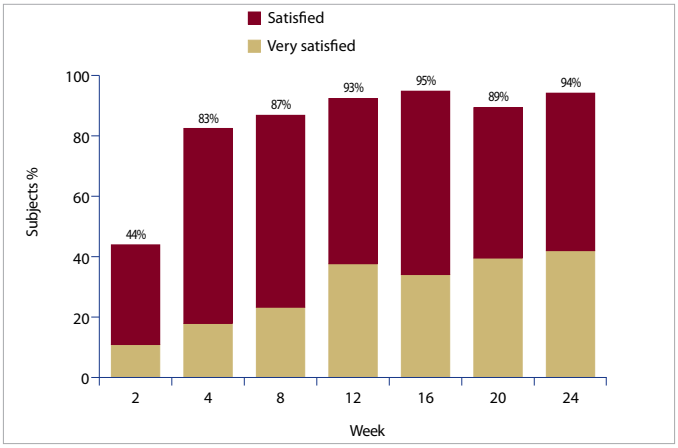
achieved with any of these agents individually and deserves to be probed in future studies.

Overall, the treatment may enhance elasticity, and reduce wrinkling and hyperpigmentation. Improvements in elasticity and wrinkling may be attributable to both the copper zinc malonate complex and to tretinoin. Copper zinc malonate has been reported to reduce the appearance of wrinkling—possibly as a result of regeneration of the elastic fiber network[19,20]—and tretinoin has been reported to improve the quality of elastic fibers, to increase collagen, and to reduce the appearance of wrinkling.[22,23] Improvements in hyperpigmentation are likely attributable primarily to the hydroquinone but also partly to tretinoin.[21,22]

One of the intents of this study was to evaluate whether or not there were differences in tolerability when each of the two concentrations of tretinoin were used—hence there was not a placebo control group. Furthermore, the subjects had moderate to severe photodamage which is a stable pathology that would not be expected to improve spontaneously. Future controlled studies, in larger numbers of subjects with varying degrees of photodamage, would be desirable.

FIGURE 4. Proportion of all subjects satisfied or very satisfied with the overall improvement in their décolletage.



CONCLUSION

The results from this study show that use of the décolletage system in conjunction with tretinoin is highly effective in improving photodamaged skin of the anterior chest and neck, achieving significant improvements within two or four weeks. This treatment is also well tolerated and results in high levels of subject satisfaction.

DISCLOSURES

Dr. Leyden is a consultant to Obagi Medical Products, Inc.

Dr. Parr was an employee of, and holds stock options in, Obagi Medical Products, Inc.

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TABLE 3.

Proportion of Subjects Achieving Different Grades of Improvement in Each Efficacy Outcome Measure (Data from Both Treatment Groups Combined)

Outcome Measure	Week 4		Week 24	
	Subjects With At Least 1-grade Improvement (%)	Subjects With At Least 2-grade Improvement (%)	Subjects With At Least 1-grade Improvement (%)	Subjects With At Least 2-grade Improvement (%)
Overall integrated assessment	73	0	95	37
Tactile roughness	78	13	97	76
Mottled hyperpigmentation	73	13	97	61
Lentigines	50	3	87	50
Fine wrinkling	78	0	100	42
Laxity	23	0	68	8
Crepiness*	25	0	71	21
Coarse wrinkling	5	0	45	3

*Crepiness=a wrinkled appearance similar to crepe paper.

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TABLE 4.

Expert Grader Scores for Erythema, Dryness, Peeling and Burning/Stinging (Bold Values Indicate Maximum Mean Scores)

Parameter	Treatment Group	Mean Score																Maximum Score Reported
		Day																
		0	1	2	3	4	7	8	9	10	11	14	15	16	17	18	21	
Erythema	Décolletage system + 0.025% tretinoin	0.0	0.0	0.0	0.2	0.0	0.3	0.7	0.4	0.5	0.7	**1.0**	**1.0**	**1.0**	0.9	0.8	0.4	4 (Days 8, 9, 14–18)
	Décolletage system + 0.05% tretinoin	0.0	0.2	0.0	0.0	0.1	0.5	0.9	0.3	0.6	0.6	**1.4**	1.3	1.3	1.0	0.8	0.3	5 (Days 15–18)
Dryness	Décolletage system + 0.025% tretinoin	0.0	0.0	0.0	0.0	0.0	0.1	0.3	0.2	0.2	0.1	**0.5**	**0.5**	0.4	0.2	0.2	0.1	4 (Days 8, 9)
	Décolletage system + 0.05% tretinoin	0.0	0.0	0.0	0.0	0.0	**0.4**	0.3	0.2	0.3	0.1	0.2	0.1	0.1	0.0	0.0	0.0	3 (Day 7)
Peeling	Décolletage system + 0.025% tretinoin	0.0	0.0	0.0	0.0	0.0	0.1	0.2	0.2	0.2	0.1	**0.5**	**0.5**	0.3	0.2	0.2	0.1	4 (Days 8, 9, 14, 15)
	Décolletage system + 0.05% tretinoin	0.0	0.0	0.0	0.0	0.0	**0.5**	0.2	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.0	3 (Day 7)
Burning/ Stinging	Décolletage system + 0.025% tretinoin	0.0	0.1	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0	**0.5**	0.3	0.4	0.2	0.1	0.1	4 (Day 14)
	Décolletage system + 0.05% tretinoin	0.0	0.0	0.0	0.0	0.0	0.2	0.1	0.1	0.0	0.1	0.4	**0.6**	**0.6**	0.2	0.2	0.1	6 (Days 15, 16)

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