

MERCULINE

SELF-CARE

AGE REVERSE SYSTEM CLINICAL STUDY

AN OPEN LABEL CLINICAL TRIAL OF A NOVEL 3 PRODUCT
ANTI-AGING REGIMEN

INTRODUCTION AND OBJECTIVE OF STUDY

Cosmeceuticals are the fastest growing sector of the skin care industry, with anti-aging products leading the growth. Marketing claims often emphasize that certain formulation guidelines will lead to better appearing, healthier skin. These factors are: the omission of potentially problematic ingredients, the inclusion of botanical and other naturally-derived ingredients, and high levels of unique actives, often referred to as “medical grade.”

The present study set out to observe subjects who followed a 3-step regimen of “medical grade” paraben free, sulfate free, dye free skin care combining high levels of unique actives with botanical and marine extracts. Subjects were assessed at baseline and every two weeks for a 12-week period with both digital photography and clinical evaluation by a board-certified dermatologist.

The objective of this study was to determine the effectiveness of the 3-step multi-ingredient regimen on improvement of four skin parameters. These parameters were lessening in appearance of lines and wrinkles, improvement in redness, evening of skin tone, and improved skin texture. After 4 weeks of twice daily use, clinical evaluation results show that the anti-aging regimen produced a significant improvement in all four clinical parameters assessed compared to baseline. A greater improvement was seen at 12 weeks.

REGIMEN PROFILE

1. Omission of problematic ingredients

Each of the products in the test regimen were:

Sulfate Free: this claim refers to the omission of the foaming agent Sodium Lauryl Sulfate, which is associated with worsening of redness, pore appearance, and breakouts.

Paraben Free: these preservatives, widely used in topical preparations, have been associated with positive breast cancer biopsies as well as allergic contact dermatitis.

Dye Free: food coloring and naturally derived dyes used in skin care formulations have been noted to cause contact dermatitis. More often than causing a rash, these dyes can enhance facial redness that is often incorrectly attributed to other conditions like rosacea and photoaging.

2. Inclusion of special botanical and marine derived ingredients

For centuries, essential oils and plant extracts have formed the basis of a myriad of medicinal remedies proven effective in various cultures. Newer botanical and marine actives that are the result of cutting-

edge extraction processes now claim remarkable rejuvenation, hydration, and skin calming benefits. Products in the 3-step test regimen incorporate chamomile and citrus essential oils, chamomile extracts, sunflower seed oil, and certified organic lilac stem cells. Also, two unique cutting-edge marine extracts from the coastal waters of France act as gene modulators to upregulate genes responsible for skin firming components including collagen, elastin, and hyaluronic acid, and to downregulate the gene responsible for synthesis of the skin aging protein, Progerin.

3. “Medical grade” actives

The term “medical grade skin care” has come to the forefront as skin care consumers turn to their physicians and skin care professionals for products they expect to be more effective than standard cosmetic company products. The distinguishing features of the medical grade products are generally high concentrations of unique, science-based actives. The present regimen incorporates active levels of Lipochroman® (the strongest* and only antioxidant that protects from both nitrogen and oxygen free radical formation), Chromabright® (a UVA/UVB photoprotective tyrosinase inhibitor that is unique in having a broad spectrum UV protective profile compared to the more popularly used fade ingredients, hydroquinone and kojic acid, both of which are UV sensitizers.), 3% tetrahexyldecyl ascorbate (a vitamin C analogue that is photoprotective against both UVA and UVB. Due to its lipophilic structure, it has superior percutaneous absorption than L-ascorbic acid, is less irritating, and is a better collagen stimulator than L-ascorbic acid).

*Results of T-Bar Assay, showing Lipochroman® 11x stronger than Idebenone on quenching oxygen freeradicals

THE REGIMEN

The 3-step regimen included a botanical cleanser, a lilac stem cell + vitamin C + marine extract serum, and a double action antioxidant moisturizer with Chromabright®.

STUDY DESIGN

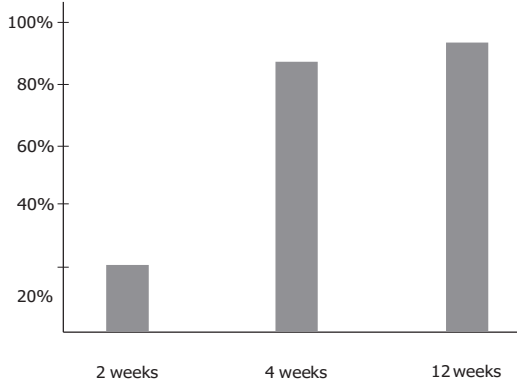
The open label study was completed by 14 women and one man, ages 37 to 75, who used the 3-part skin care regimen twice daily for 12 weeks. Subjects stopped all other skin care products* and had no other treatments for at least one month prior to or during the study. Subjects were assessed both photographically as well by physical exam by a board-certified dermatologist at baseline and biweekly for a period of twelve weeks, during which they applied the three products twice daily.

*They were advised to use their usual SPF product if they were going to be outdoors

RESULTS

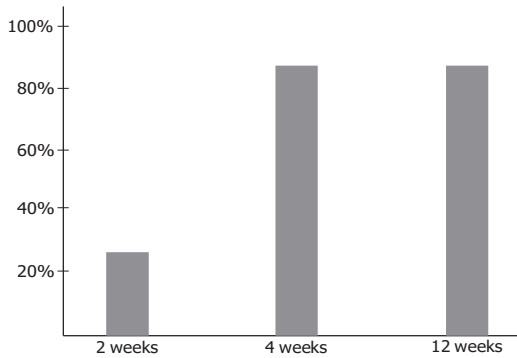
All testers reported that the products were well tolerated for the 12 weeks.

Improvement in Fine Lines and Wrinkles

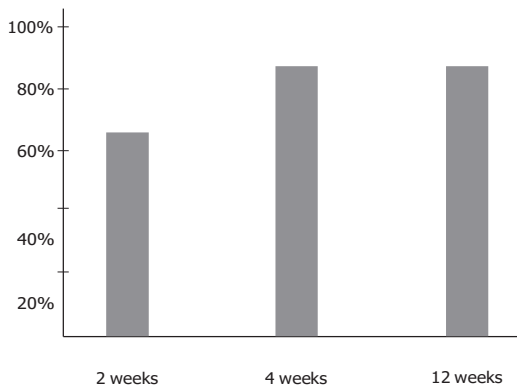


All 15 testers had visible fine lines and/or wrinkles at baseline. By four weeks, 87% showed visible improvement in the appearance of lines and wrinkles. Of note, the two testers who did not show improvement in this parameter were age 70 and 75 and had very severe photodamage and deep wrinkling at baseline. The 75 year old did show improvement at 12 weeks.

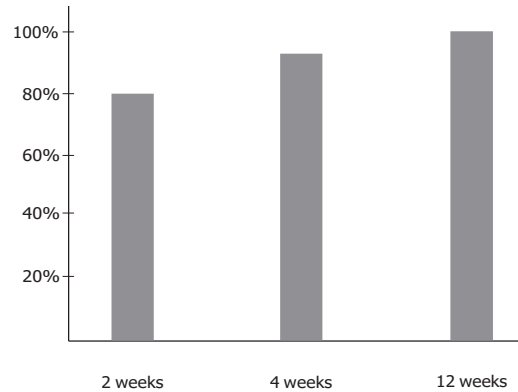
Improvement in Skin Tone



Improvement in Redness



Improved Skin Texture



DISCUSSION

The present study shows strong evidence that these three products used twice daily as a skin care regimen can produce significant visible improvement in certain parameters of appearance.

The double action antioxidant, Lipochroman[®], has been shown on T-Bar Assay to have the highest activity against oxygen free radicals and it also is active against nitrogen free radicals. Since nitrogen makes up approximately 90% of the atmosphere and since Lipochroman[®] has the strongest activity against oxygen free radicals, the visible improvement in skin signs of photo- and environmental aging is arguably quite predictable even at 4 weeks.

Also, the tyrosinase inhibitors (lilac stem cells, tetrahexyldecyl ascorbate, and Chromabright[®]) in the regimen all are photoprotective, which may well account for the lessening of redness and evening of tone noted as early as 4 weeks. The two marine extracts (Brown algae and Undaria) that are DNA modulators seem to account for the overall rejuvenation noted by all testers by week 4 (due to lessening in skin Progerin, the aging protein, as well as significant lessening in lines and even some nasolabial fold depth [due to gene activation of the genes responsible for synthesis of hyaluronic acid, collagen, and elastin]).

The test group included two subjects of 70 and 75. Today's anti-aging consumer has shifted to include women in their seventies and beyond. We advocate using some testers who are past the typical upper age of 55 or 60 to get a more accurate sense of results when products and regimens are used in the marketplace.

RESULTS



LINES AND WRINKLES

This 58-year-old female complained of deep forehead lines, uneven pigment, rough skin texture and a tired, older look to her skin at baseline. She had tried innumerable physician dispensed and department store skin care products to no avail. Note the lessening in appearance of forehead lines, improved skin texture and evening of skin tone in the after photo.



UNEVEN SKIN TONE

This 54-year-old male had a more than 30 year history of facial sensitivity, uneven tone and roughness. He had been treated by multiple dermatologists and used topical steroids, topical and oral antibiotics and other rosacea therapies all to no avail. At baseline, he was using a non-chemical SPF 40 in the morning and 40% Zinc Oxide paste at bedtime. Note the lessening of red blotches and scaling and improvement in texture in the after photo.



TEXTURE

This 49-year-old woman was using a \$500 skincare regimen at baseline with issues of uneven pigment and redness, skin dullness, and lines around her eyes. Note lessening of discoloration and redness, smoother skin texture and lessening of crow's feet in the after photo.



This 75-year-old woman complained of deep nasolabial folds, poor skin texture, and moderate acne scarring as the residual of her teenage and adult acne. Note smoother texture and lessening in the appearance of cheek acne scars and lessening in nasolabial depth in the after photo.

REDNESS



This 37-year-old woman had tried various complicated regimens with many steps to no avail in the attempt to resolve her complaints of facial redness, bumpy texture, uneven pigment and fine lines. Note improvement in redness, smoother texture, more even pigment in the after photo.



This 70-year-old woman complained of redness and flaky and rough texture to her skin with well-defined keratoses evident on physical exam at baseline. Note lessening in the size of the cheek keratosis as well as fading of undereye discoloration in the after photo.