

CLINICAL STUDY REVEALED COSMETIC SERUM
INCREASED SKIN ELASTICITY, LIGHTENED
DARK SPOTS AND REDUCED WRINKLES IN
FEMALE SUBJECTS OVER FORTY YEARS WITH ALL
PARAMETERS SHOWING HIGHLY STATISTICALLY
SIGNIFICANT POSITIVE CHANGES

Kimberly Purdy Lloyd M.S., Timothy Ulrichs Ph.D.,
Lars Rütter Ph.D., Ulrike von Hehn Dipl.-Math

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BACKGROUND

Today there is a variety of naturally occurring extracts and cosmetic ingredients that are showing promise to support skin health, skin texture and improve appearance. Human skin fibroblasts may show positive responses in cell culture systems to ingredients, however it is also necessary to evaluate formulas in a clinically controlled study. Safety and effectiveness need to be evaluated in human subjects as well as theoretical and safety profile evaluations. Formulas may contain numerous active ingredients. It is important that the formula be tested in actual subjects by professionals with technologies capable of evaluating skin parameters.

SEVEN SWISS ALPINE PLANTS KNOWN FOR SKIN CONDITIONING AND BRIGHTENING

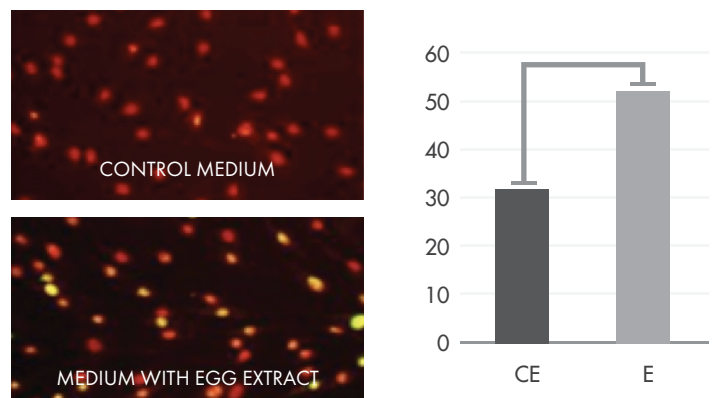


OBJECTIVE

Over time the effects of gravity, environmental factors and sun exposure result in skin sagging, appearance of brown spots and wrinkle formation. A recent formula, Lamiderm[®] (LifePharm, Inc., Lake Forest, CA) was created using ingredients that had shown prior lightening effects. Also, a proprietary fertilized chicken egg extract was added to the formula. The proprietary fertilized egg extract was recently tested in human fibroblast skin cultures showing significant increased production of elastin, collagen and fibronectin fibers.

Growth factors known to stimulate dermal fibroblast activity and skin matrix fiber production were identified in the egg extract. It was of interest to observe if the formula applied to 20 subjects in a dermatology monitored study would show safety and effectivity.

EGG EXTRACT STIMULATES PROLIFERATION OF HUMAN SKIN FIBROBLASTS



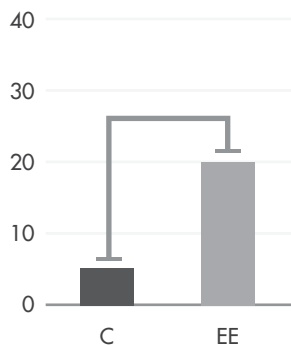
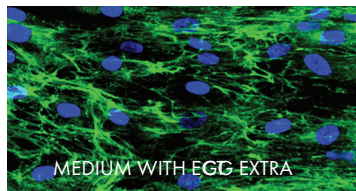
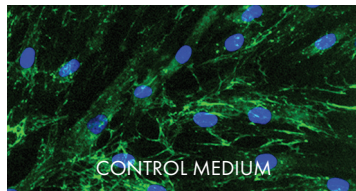
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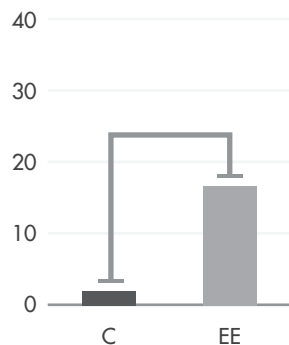
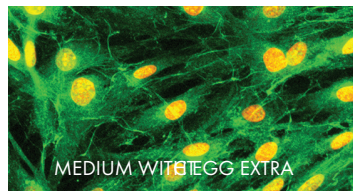
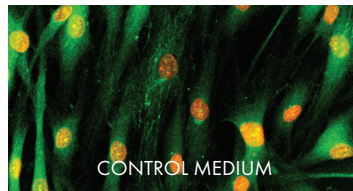
OBJECTIVE (CONTINUED)

HUMAN SKIN FIBROBLASTS TREATED WITH LIFEPHARM EGG EXTRACT CONTAINING GROWTH FACTORS AND LYSYL OXIDASE

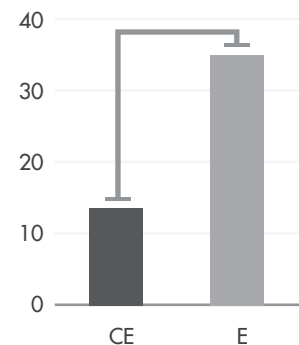
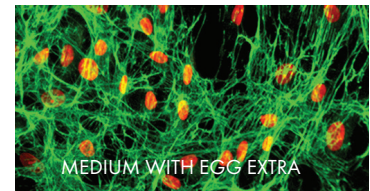
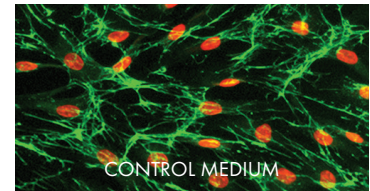
COLLAGEN
UP TO **250%** IMPROVEMENT
AFTER 3 DAYS



ELASTIN
UP TO **200%** IMPROVEMENT
AFTER 3 DAYS



FIBRONECTIN
UP TO **350%** IMPROVEMENT
AFTER 3 DAYS



METHODS

Twenty healthy subjects who were aged 40 years and older with crow's feet next to the eyes and age spots on the neck and upper chest were selected and signed informed voluntary consent. The exclusion criteria were that subjects had no pathological skin disorders including skin inflammation, chronic diseases, drug use that would interfere with skin reactions, no allergies, no known cancer, no pregnancy or lactation and no use of tanning bed or sunbathing during the study period. Subjects were instructed to apply the serum to their clean face in the morning and at night before sleeping.

Dermatesi[®] GmbH of M  nster Germany performed the tests and dermatologists and allergologists monitored and recorded outcomes. Skin elasticity measurement using a state-of-the-art cutometer is based on the suction/elongation principal. The cutometer instrument (MPA 580 Fa. Courage+Khazaka electronic GmbH) generates a local low-pressure situation which is manually adjustable. The skin area is sucked into a space of the sensor and the depth of the skin penetration is measured by the sensor without contact to the skin. Afterwards the low pressure is turned off and the skin can return into its original form. Algorithmic curves from monitored data reveal the visco-elastic condition of the skin. All subjects were measured prior to starting the serum application and then at the end of the four-week application period. R2-values were measured and analyzed for each subject.

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METHODS (CONTINUED)

Age spots (L. Lentiginos seniles, Lentiginos solares) are blemishes on the skin associated with aging and exposure to ultraviolet radiation from the sun. The used spectrophotometer CM 700d, of the company Konika Minolta Sensing allows high-precision measurements using standard illuminate (CIE-Standardized light type C). A sensor cell measures the spectral reflection for different wave lengths or a narrow range of wavelengths of the object of which is to be evaluated. A minicomputer of the spectrophotometer uses these reflection data to calculate the standard color values enabling the numerical depiction of the results. The current system used to give the coordinates a color system is the L*A*B* color space (1976) and corresponds to the perceived color characterization of humans and is standardized in the EN ISO 11664-4. The brighter the pigmentation spot the higher is the ITA° values, hence a bleaching effect is characterized by an increased ITA° value. ITA° values were taken prior to starting the serum application and at the end of the four-week application period.

Wrinkle depth was measured with PRIMOS optical 3D measuring device which uses the so-called digital stripe projection technique as the optical measurement procedure. In this measurement method a pattern of parallel stripes is projected onto the surface of the skin and recorded. The 3 D measurement effect is achieved because the slightest differences in the height of the surface of the skin deflects the projected parallel stripes so that these deflections represent a qualitative and quantitative evaluation. In the evaluation, mathematical algorithms are applied which were originally developed and used for the high-precision optical measurements for 3 D measurement of the skin to build a high precision 3 D profile of the surface of the skin. This system also allows the possibility to fix the measurement position on the surface of the skin before and after treatment with a precision of 1/10th of a pixel which, using a field of measurement of 10 X 8 mm² and a camera with 640 x 480 pixels corresponds to a precision of positioning of approximately 1 µ. The measuring accuracy is ≥ 5 µm. With the PRIMOS software the changes in structure of the epidermis can be classified quantitatively with the aid of various standardized surface measurement parameters in accordance with DIN (Deutsche Industry Norm, German Industrial Standards) and ISO (International Standards Organization). The profile of the cut view used here serves to provide the depth of a single wrinkle. The skinfold depth can be measured by determining the distances. The skinfold depth values were taken prior to starting the serum application and at the end of the four-week application period.

TEST SUBJECTS AGES 40-66

NAME	GENDER	AGE	SKIN TYPE
ArPe	Female	64	Dry
BeSo	Female	43	Very Dry/Sensitive
BuKl	Female	61	Dry/Sensitive
BuSi	Female	51	Dry
DeKa	Female	51	Normal/Sensitive
GaDo	Female	66	Normal/Sensitive
HaEl	Female	60	Dry/Sensitive
KeUl	Female	52	Dry/Sensitive
Kuln	Female	61	Dry
LaBa	Female	61	Very Dry/Sensitive
NiHe	Female	66	Dry/Sensitive
PoAs	Female	57	Dry
RaMe	Female	58	Dry/Sensitive
RiMa	Female	62	Dry
ScAn	Female	52	Dry/Sensitive
RoSc	Female	57	Dry
SeSt	Female	43	Normal
StIl	Female	65	Dry
TeLu	Female	40	Dry/Sensitive
WeAn	Female	60	Combination

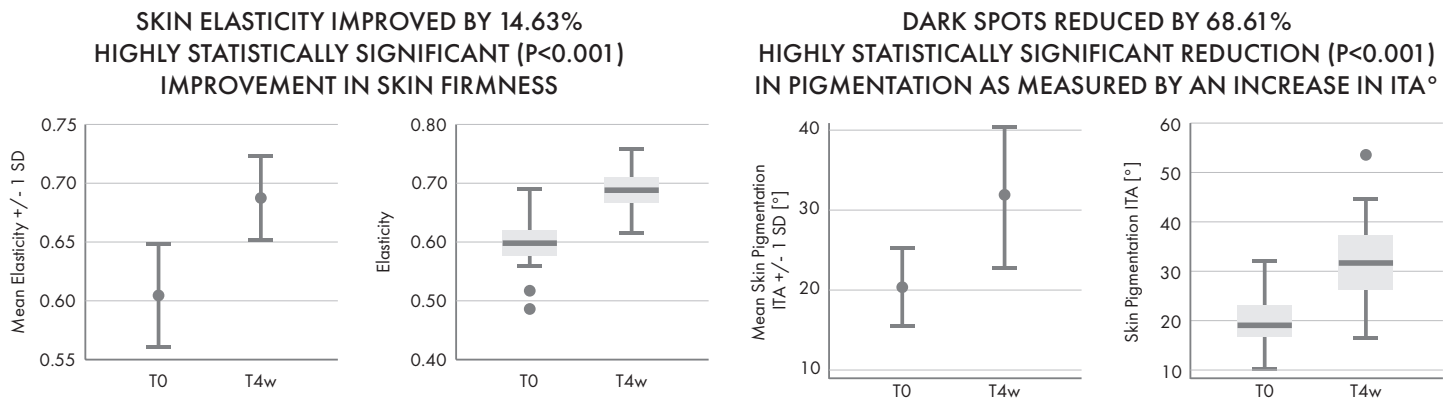
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RESULTS

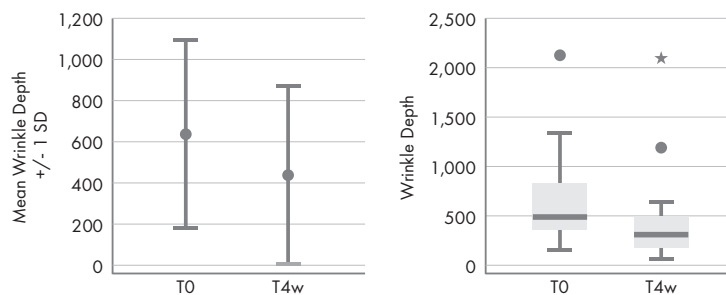
Dermatological examinations showed that all study participants had healthy skin by dermatological standard and criteria. During the study no complaint of any pathological skin disorder was reported or observed. Interruptions of test and or medical intervention were not necessary. During the final dermatological examination there was no evidence of any pathological skin disorder in any subject. A documented report showed all ingredients and concentration levels safe by European Union standards and criteria.

Statistical significance was performed by Medistat[®] GmbH Medizinische Statistik, Kronshagen, Ulrike von Hehn. Skin pigmentation as measured by the change of the ITA[°]-value after 4 weeks was an averaged reduction by 68.61%. The matched pairs t test resulted in significant reduction in pigmentation after 4 weeks as compared to baseline ($p < 0.001$).



It was shown an averaged wrinkle depth reduction of 31.77% (average of decrease by $-180.24 \mu\text{m}$). The decrease in wrinkle depth reduction between baseline measurement and after 4 weeks was statistically significant using Wilcoxon matched pairs test at $p < 0.001$. Skin elasticity improved by averaged values of 14.63% and showed a significant increase in elasticity between baseline measurement and the measurement after 4 weeks using a Matched samples t test ($p < 0.001$).

**WRINKLE DEPTH REDUCTION IMPROVED BY 31.77%
HIGHLY STATISTICALLY SIGNIFICANT CHANGE ($P < 0.001$)
THE AVERAGE CHANGE IN WRINKLE DEPTH WAS A
DIFFERENCE OF $-180.24 \mu\text{m}$.**



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CONCLUSION

The Lamiderm formula showed that all measured skin parameters met highly statistically significant improvement ($p < 0.001$) as an application for reducing dark spots, reducing wrinkle depth, and improving skin elasticity. All dermatological evaluations showed that the product caused no untoward side effects and was well tolerated. No subject experienced any allergic reaction to the product application. It is of relevance that one topical formula showed this much positive outcome on three separate skin aging parameters when used twice daily in 4 weeks as measured by a quality dermatological clinic and laboratory that specializes in this area of dermatological testing. Also, Dermatest grants a "3 Star" rating for safety evaluation of the products they test. An additional "2 Star" grading system is granted by Dermatest if the product has also met performance and efficacy testing whereby the cosmetic product shows positive outcome of appearance parameters measured. Lamiderm Apex cosmetic serum received the "5 Star Seal of Excellence" rating indicating absolute safety of ingredients according to European Union Standards for a cosmetic.

- 3 Stars are given for safety
- 36-page safety report
- Met high European standards
- High standards of safety
- No breakouts, no allergic reactions
- 2 Stars are given for efficacy
- Product performed in wrinkle reduction, elasticity, and dark spot reduction
- Non-allergenic
- Dermatologist tested



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