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SKIN RESEARCH CENTER

THE EFFECT OF AN AMINO ACID COMPLEX ON THE BIOMECHANICAL BEHAVIOR OF FACIAL SKIN

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ABSTRACT

The Effect of an Amino Acid Complex on the Biomechanical Behavior of Facial Skin. Rube J. Pardo, Ph.D., M.D., Greg Skover, Ph.D., Florence Foucauld, M.D., Mitchel P. Goldman, M.D. and Richard E. Fitzpatrick, M.D.

The ability to measure the response of the skin, non-invasively, following the application of pharmaceutical and chemical compounds has been limited to photographic, microscopic and spectroscopic analysis. These methods merely freeze a moment in time rather than evaluating the properties of a living, dynamic tissue. An instrument that analyses the responsiveness of the skin during stress was used to demonstrate that application of a skin moisturizer containing an Amino acid complex significantly alters the behavior of skin in comparison to a "placebo moisturizer." A half-face study of 15 female subjects, between 30 and 60 years old, were enrolled for a one-time application of the moisturizer, with and without the Amino acid complex, to each half of their face following a randomization code. Each subject washed her face with a soap-free, non-foaming cleanser, before baseline measurements were recorded on the forehead and cheek. Subjects applied 1-1.5 grams of moisturizer per side and waited for at least one hour before measurement. Measurements were taken at 1, 4, and 8 hours by attaching the test chamber to the skin with an adhesive ring. The instrument applied a linear negative pressure, at a rate of 10 mmHg/sec; over one centimeter of skin until 150 mm Hg was achieved. An infrared targeting laser detected the vertical deformation of the skin enabling the instrument to automatically calculate and display biomechanical properties of the skin including, ultimate deformation, laxity, elasticity, stiffness, and energy absorption. Pressure and deformation were graphically displayed in real time and using embedded biomechanical algorithms the data on the aforementioned parameters was calculated by averaging three repetitive cycles. Results demonstrate that the moisturizer containing the Amino acid complex significantly decreases skin stiffness and increases energy absorption at both locations at the one-hour time point. The skin returns to baseline levels within four hours. Visual inspection of the face, by an experienced evaluator blinded to the moisturizer ingredients, detected a difference in skin appearance induced by the amino acid complex 60% of the time. These results indicate that we now have the ability to measure the biomechanical properties of th skin during dynamic stress and that the amino acid complex significantly alters the compliance of the skin during use.

BACKGROUND

A number of skin care products and regimens exist today that claim to enhance the biomechanical qualities of the skin. One such product is an amine complex that proposes to improve skin tone following application. The effect is cosmetic and lasts for only a few hours. It is described as a lifting or tightening of the skin by previous subjects. Unfortunately for this and other cosmeceuticals, many of these claims are based on anecdotal evidence and lack well defined clinical protocols and appropriate measuring devices.

The BTC-2000 Dynamic Skin Analyzer is an instrument designed to measure the elastic deformation of skin during dynamic stress. A measuring chamber is attached to the skin using an adhesive ring, one centimeter in diameter, that isolates a specific area of skin and minimizes skin creep during analysis. The instrument applies a linear negative pressure, at a predetermined rate until a maximum pressure is achieved for a specified number of cycles. An infrared targeting laser detects the vertical deformation of the skin enabling the instrument to automatically calculate and display pressure and deformation in real time. Biomechanical properties of the skin including, ultimate deformation, laxity, elasticity, stiffness, and energy absorption are calculated using embedded biomechanical algorithms by averaging the data collected from the predetermined repetitive cycles.

The elastic deformation of the skin is the maximum amount of displacement obtained at the maximum pressure. Stiffness and energy absorption are two important biomechanical characteristics used to describe the stiffness and compliance of a material. Stiffness is the slope of the stress/strain curve and energy absorption is the area underneath the curve generated between the minimum to the maximum point on the curve. As the slope increases so does the stiffness of the material. The compliance of a material describes its softness or firmness. As energy absorption increases so does the softness of the material. The more resistant a material is to stress the greater is its perceived hardness. In the case of skin, a tighter skin has a greater slope and a higher stiffness. Tight skin would also have a low compliance and be considered hard or firm. However these biomechanical definitions may not translate into the applied connotations of skin tone and are used here to describe the structure of the skin and not its aesthetics.

OBJECTIVES

- Measure the ability of a cosmeceutical formulation to alter the biomechanical properties of facial skin
- Determine the duration of action of the formulation on the biomechanical properties of the skin one, four and eight hours after application in comparison to a placebo moisturizer

OUTCOME VARIABLES

- Skin Stiffness
- Energy Absorption
- Visual Appearance
- Clinical & Subject Assessment

STUDY DESIGN

The study was conducted as a single exposure, randomized, placebo controlled, ½ face study in healthy female subjects. Subjects meeting all inclusion and no exclusion criteria were chronologically enrolled in the study. The active or placebo moisturizer was disguised from the patient's knowledge. All subjects washed their faces with a soap-free, non-foaming cleanser before the initial clinical evaluation, biomechanical measurement and photography. Subjects applied one gram of the coded test article to the appropriate side of the face as designated by the randomized, enrollment form. Skin assessment was performed one, four, and eight hours after application. The subject was asked to refrain from vigorous activities or excessive sun exposure during the study. Upon completion of the assessment the subject washed her face and was released from the study.

SUBJECT SELECTION

- Non smoking females over the age of 30 and under the age 60 years old in good health.
- Subjects with skin classified as Fitzpatrick skin type IV or less.
- Subjects have not had phenol peels, dermabrasion, or laser resurfacing procedures.
- Subjects without facial nerve disorders.

TEST FORMULATIONS

Active Moisturizer
Moisturizer with NTP Complex™
LOT JJ11021A

Placebo Moisturizer
Moisturizer
LOT # JJ10302P

Prepared by: HNC Products, Inc. Clinton, IL 61727

TEST INSTRUMENTATION

BTC-2000™
SRLI Technologies, Nashville, TN 37203

RESULTS

Panel Demographics

The subject's average age was 43 years old, the highest frequency occurring in the thirty years old age group. The subject's skin type evenly distributed between Fitzpatrick Skin Type II, III, and IV. The subject's average Body Mass Index was 23.6 ranging between 19.0 kg/m² and 30 kg/m².

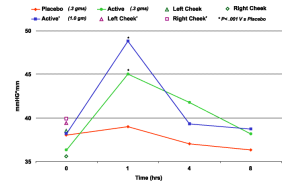
Biomechanical Assessment

The skin on the right and left cheek was measured before application of the test articles. The Active moisturizer was tested in two doses, .3 gram and 1 gram in two panels of fifteen subjects each once against placebo and once against an alternative moisturizer. Skin stiffness is in units of mmHg/mm and represents the greatest slope of the Stress-Strain curve. Skin energy absorption is in units of mmHg*mm and represents the area under the curve. The distribution of right and left cheek assigned to test the Active and Placebo moisturizer changed the baseline stiffness and energy absorption. Analysis of the measurements indicates that cheek skin was not statistically different at baseline; therefore, significant changes in these parameters are not the result of the population distribution and may be attributed to the application of the test articles. Figure 1 and 2 demonstrate that the Active moisturizer significantly decreased skin stiffness and increased skin energy absorption in one hour. Both Skin Stiffness and Energy Absorption returned to approximately baseline levels at the four-hour evaluation and stabilized at these values at the final, eight-hour evaluation.

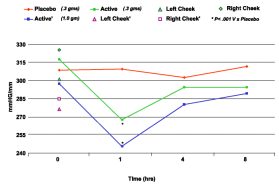
Clinical Assessment

The clinician described one side of the face as appearing shinier than the other, seven out of eight times it was the side treated with the Active Moisturizer. Subjects were asked if one side of their face appeared more youthful than the other side at any time during the day. Four subjects chose the side treated with the Active Moisturizer and one subject chose the side treated with the Placebo Moisturizer. The other subjects could not distinguish a difference between either side of the face. Review of the comments indicates four subjects had a positive reaction and seven had a negative reaction to the formulations. The major unsolicited response was that the formulations felt sticky.

THE EFFECT OF A ONE TIME APPLICATION OF NTP COMPLEX FORMULATION ON THE ENERGY ABSORPTION OF CHEEK SKIN (N=15)



THE EFFECT OF A ONE TIME APPLICATION OF NTP COMPLEX FORMULATION ON THE STIFFNESS OF CHEEK SKIN (N=15)



APPLICATION OF ACTIVE VS PLACEBO FORMULATION IN A HALF-FACE EVALUATION

Time: 0 Time: 1

CONCLUSIONS

These data indicate that the model and the measurement are effective in detecting significant alternations in the biomechanical mechanical properties of facial skin following application of cosmeceutical formulations. This formulation, at the concentration tested, induces a significant decrease in skin stiffness and increase in energy absorption. These changes occur within one hour of application and resolve within four hours.

The BTC-2000 provides results that are objective and quantitative and enable a higher order of accuracy and statistical power to be used than traditional clinical evaluation. The biochemical relevance is yet to be determined, however may indicate a redistribution of organized water in the extracellular matrix creating a more pliable structure.