

EFFICACY OF NOVEL GROWTH FACTOR CONTAINING SKIN CREAM IN THE TREATMENT OF FACIAL ELASTOSIS

Michael H. Gold¹, Julie Biron¹, Mitchel P. Goldman²

¹ Tennessee Clinical Research Center, Nashville, TN ² La Jolla Spa MD, La Jolla, CA

ABSTRACT

This two-center study was designed to evaluate the efficacy of a novel growth factor containing skin cream for skin aging. It contains processed skin cell proteins, which is a naturally balanced mixture of growth factors. Facial skin quality was assessed visually, by photography and by phase-shift rapid in vivo measurement of skin. 18 subjects (between 38 to 65 years of age) completed the study. After twice daily application for two months, 83% of the subjects showed an improved appearance of wrinkles in the eye area, while 50% of the subjects showed an improved appearance of wrinkles in the mouth area as assessed visually. In addition, 67% and, respectively, 56% of the subjects showed an improved cheek or chin skin texture. A subject self evaluation of facial skin quality together with the photographic assessment and the quantitative analysis of skin surface topography confirmed those observations. This study thus suggests that appropriate growth factor mixtures are an effective option for helping to improve the signs of facial elastosis.

INTRODUCTION

Aged or photo-aged skin manifests in cutaneous dryness, skin laxity, atrophy, fine and deep wrinkles as well as pigmentation changes. On a molecular level, aged skin is characterized by the presence of abnormal, fragmented collagen fibers and diminished total collagen content. Some growth factors are known to promote dermal fibroblast and keratinocyte proliferation and to induce extracellular matrix formation including fibrellar collagen. Besides their central role in wound healing¹, growth factors may therefore be also beneficial in reducing signs of skin aging.

The goal of the two-center study was to investigate a novel growth factor containing skin cream to help improve appearance of aged facial skin. The cream was developed at the University Hospital of Lausanne, Switzerland, inspired by fetal skin's unique ability to heal without scarring. It contains processed skin cell proteins (PSP), which is a naturally balanced mixture of skin nutrients including 18 identified growth factors and many other cytokines. The mixture is obtained through a biotechnology process using cultured fetal skin cells from a dedicated cell bank.

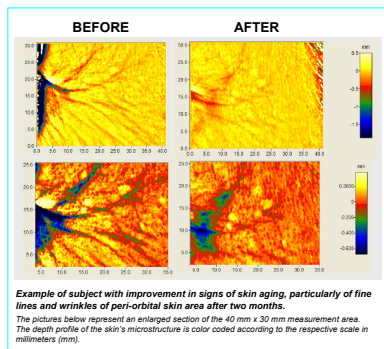
RESULTS

Of the 20 subjects enrolled (10 per center), 18 subjects averaged 52 ± 8 years of age (between 38 to 65 years) completed the study. Two subjects dropped out of the study for product unrelated reasons.

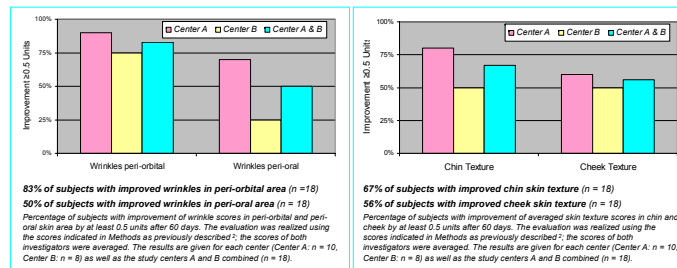
Photographic Evaluation



Skin Surface Topography Evaluation



Investigator Assessment



Subject Assessment

	Center A	Center B	Center A & B
Global Texture (Q1)	40%	50%	44%
Wrinkles Eye Area (Q2)	50%	38%	44%
Wrinkles Mouth Area (Q3)	40%	50%	44%
Cheek Tightness (Q4)	60%	38%	50%
Skin Thickness (Q5)	50%	25%	39%

About half of the subjects observed improved facial skin conditions by at least one unit after two months.

Percentage of subjects with improved facial skin scores by at least one unit after 60 days (Center A: n = 10, Center B: n = 8, center A & B: n = 18). The subjects were asked to complete the questionnaire given in Methods before and after using a processed skin cell proteins (PSP) containing skin cream for 60 days.

METHODS

Design of Two-Center Study as Approved by Ethical Committee

Inclusion criteria

- Female between 35 to 65 years of age of good general health not nursing or pregnant
- Demonstrable facial wrinkling in eye and lip skin area corresponding to Grade 2 or higher in Rao-Goldman's 5-point wrinkle scale²

Exclusion criteria

- Any active or any history of skin disease affecting the face
- Any microdermabrasion, light and medium skin peels within one month, any non-ablative laser, light or radio-frequency treatments in face within three months, any dermabrasion, deep skin peels, ablative laser treatments, Botox® or filler injections, or cosmetic surgery in face within six months prior to study begin

Treatment regimen

- Application of processed skin cell proteins containing skin cream (provided by Neocutis, Inc.) in morning and evening to face over a period of two months (60 days) by subject under in use conditions.

Evaluations at baseline and after 60 days

- Photographic assessment using VISIA-CR Imaging System (Canfield Scientific) under standardized conditions (position of face, lighting, photographic settings)
- Assessment of surface topography of peri-orbital area by optical profilometry using PRIMOS-3D System³ (GF Messtechnik, Germany; Canfield Scientific)
- Visual assessment of facial wrinkles in peri-orbital and peri-oral skin areas using Rao-Goldman's 5-point wrinkle scale² by two independent investigators: (1) wrinkle absent, (2) shallow, but visible, (3) moderately deep, (4) deep with well-defined edges, and (5) very deep with redundant folds
- Visual assessment of skin texture of chin and cheek using a 4-point skin texture scale by two independent investigators: (1) smooth and soft, (2) slightly coarse and grainy, (3) coarse and grainy, and (4) bumpy and uneven
- Self assessment of quality of facial skin by subject using following questionnaire (scale for scoring given in parenthesis):

- Q1: Do you feel your face's skin texture is (1) smooth and soft, (2) slightly coarse and grainy, (3) coarse and grainy, or (4) bumpy and uneven?
 Q2: Do you feel that your facial lines or wrinkles around the eye area (1) not visible, (2) shallow, but visible, (3) moderately deep, (4) deep, or (5) very deep?
 Q3: Do you feel that your facial lines or wrinkles around the mouth area (1) not visible, (2) shallow, but visible, (3) moderately deep, (4) deep, or (5) very deep?
 Q4: Do you feel your cheek skin is (1) very tight or firm, (2) tight, (3) little tight, (4) loose, or (5) very loose and baggy?
 Q5: Do you feel that your facial skin thickness is (1) thick, (2) normal, (3) thin, or (4) very thin?

CONCLUSIONS

The two center study revealed that a novel growth factor containing cream was shown to effectively reduce signs of aging after a rather short period of use. The cream contains processed skin cell proteins (PSP), which is the most complete growth factor mixture currently available. After twice daily application for two months, 83% of the subjects showed an improved appearance of wrinkles in the eye area, while 50% of the subjects showed an improved appearance of wrinkles in the mouth area as assessed visually. Improved skin texture of chin and cheek was seen in 67% and 56% of the subjects, respectively. Photographic assessment together with quantitative analysis of skin surface microstructure or topography by phase-shift rapid in vivo measurement of skin using the PRIMOS device confirmed those observations. About half of the subjects noticed that their facial wrinkles were less apparent (by at least one unit on the 5-point scale) and reported improved skin tightness and texture (by at least one unit on the 4-, or 5-point scale), what confirms the investigator's observations. Concluding, this study suggests that appropriate growth factor mixtures can be successfully used to help reduce the signs of facial elastosis.

REFERENCES

- Werner S. and Grose R., Physiol Rev 2003, 83, 835-870
- Rao J., Ehrlich M. and Goldman M.P., Cosmetic Dermatol 2004, 17, 705-713
- Jacobi U. et al., Skin Res Technol 2004, 10, 207-214

FUNDING

Study 100% funded by Neocutis, Inc., San Francisco, CA