

EFFICACY OF GROWTH FACTOR SOLUTION IN CONJUNCTION WITH MICRONEEDLING THERAPY

Christopher Dannaker M.D., Richard Jin, M.D. Ph.D, Jungju Na, M.D. Ph.D

Abstract:

BACKGROUND: Growth factors in cosmeceuticals possess the potential to stimulate processes within the dermis to decrease wrinkles and brighten skin, improving the overall complexion. We recently developed GF Rejuvenating Complex, which contains a proprietary formulation of growth factors designed to diminish the signs of aging and sun damage by accelerating DNA repair. It also contains antioxidants to prevent free radical damage. We hypothesized that GF Rejuvenating Complex, used in conjunction with SkinStamp VMT (Vertical Micro-Needle Therapy) to enhance penetration, improves the overall complexion of the skin.

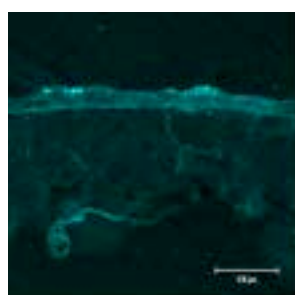
METHODS AND RESULTS: GF Rejuvenating Complex used in conjunction with SkinStamp VMT resulted in a 62% ($p < 0.005$) decrease in wrinkles. Of 14 subjects, 13 (93%) showed a decrease in wrinkles. Nine of 14 (63%) subjects recognized lightening of their skin tone.

CONCLUSIONS: These findings demonstrate GF Rejuvenating Complex combined with SkinStamp VMT results in significant improvement of wrinkle appearance. More than half of subjects experienced the lightening effect of the treatment.

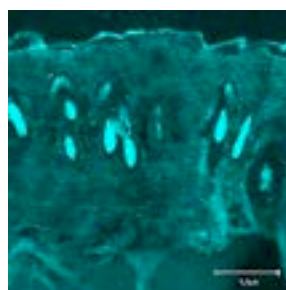
INTRODUCTION: Many studies have shown the beneficial effects of growth factors on wound healing. Growth factors are naturally occurring proteins that stimulate cell growth, proliferation, and differentiation. They may act as signaling molecules, affecting the transcriptional and translational regulation between cells. Wound healing is a complex process characterized by inflammation, proliferation of new cells, and remodeling. During wound healing, the skin relies upon the complex interactions of growth factors to regenerate dermal and epidermal tissue. The synergistic effects of growth factors result in autocrine and paracrine stimulation of cells throughout the wound healing process. Among their many effects, growth factors are responsible for angiogenesis, the formation of new blood vessels from endothelial cells. In addition, growth factors stimulate collagen deposition and cell proliferation. The dynamic interactions of growth factors with each other and cells in the dermis results in rejuvenation of the skin. Cillum Biomedical Inc. has developed a growth factors solution, which contains a proprietary formulation of growth factors and work synergistically to accelerate DNA repair, ultimately resulting in an improved complexion.

The study has incorporated the SkinStamp VMT (Vertical Micro-Needle Therapy) system to the treatment to facilitate the delivery of the growth factor-rich GF Rejuvenating Complex to the dermis. The SkinStamp procedure creates micro-channels in the skin to allow improved penetration of the GF Rejuvenating Complex. The study shown in Figure 1 proves that the SkinStamp VMT is an effective device for the transdermal delivery of solutions. The intensity of this non-ablative procedure serves to increase the efficacy of the patient's rejuvenation treatment by influencing dermal remodeling through stimulation of the wound healing process.

Subject	Mouse/male
Solution used	Hoechst 33342 (glowing substance)
Camera	Confocal Microscope (LSM meta 510, Carl Zeiss, Germany)



Solution applied without SkinStamp



Solution applied with SkinStamp (magnified image)

Figure 1. Transdermal Delivery Study

MATERIALS AND METHODS: Fifteen subjects between 21 and 69 years of age were enrolled in a 4-week clinical study to evaluate the efficacy of GF (Rejuvenating Complex combined with the SkinStamp VMT procedure). Eleven subjects were Caucasian, two subjects were Hispanic, one subject was Asian, and one subject was African American. Subjects who had any medical procedure such as laser resurfacing, microdermabrasion, CO₂ fractional laser treatment, plastic surgery to the test areas, Botox, or filler injections within the past 12 months prior to the start of the study were excluded.

The VISIA® Complexion Analysis System (Canfield Imaging Systems) was used to analyze patients before and after treatment. This system utilizes multi-spectral imaging and analysis to capture and measure key visual information for factors affecting complexion health and appearance. The pictures of each subject were taken before and after once-a-week SkinStamp VMT procedures during four weeks of study. For the purpose of performing statistical analysis, both wrinkle counts and VISIA wrinkle scores were used.

RESULTS: Of the 15 subjects enrolled in the study, 14 subjects averaged 50.8 years of age (between 21 and 69 years) completed the study. One subject left voluntarily due to reasons unrelated to the study.

Photographic Assessment: Pictures of each subject were taken before and after the SkinStamp VMT procedures during four weeks of study. Before and after photos are shown in Figure 2. Subjects showed an approximate 62% reduction ($p < 0.005$) in score of wrinkles as analyzed using the VISIA® Complexion Analysis System and 54% reduction ($p < 0.0007$) in wrinkle count. Thirteen of 14 subjects (93%) showed a decrease in wrinkles. Nine of 14 (64%) people showed a lightening of their skin tone.

DISCUSSION: Growth factors possess the ability to facilitate wound healing via transcriptional and translational mechanisms. Growth factors may participate in the skin rejuvenation at different levels due to their interactions with their receptors and other modulators. Many processes such as angiogenesis, collagen deposition, and remodeling contribute to the skin rejuvenation process. Cellum Biomedical Inc.

developed GF Rejuvenating Complex specially formulated with growth factors, antioxidants, natural extracts, and skin nutrients to accelerate the wound healing process and improve skin rejuvenation.

In order to effectively deliver the optimal concentrations of growth factors in the GF Rejuvenating Complex, we included the SkinStamp VMT procedure. The SkinStamp VMT procedure created micro-channels, allowing the GF Rejuvenating Complex to penetrate down into the dermal layer of the skin to maximize its effect.

From the study, we conclude that GF Rejuvenating Complex used in conjunction with SkinStamp VMT significantly reduces the number and appearance of wrinkles and the appearance of pigmentation, resulting in improved skin rejuvenation.

Figure 2. Photographic assessment of before and after images taken of study subjects.



Before



After



Before



After



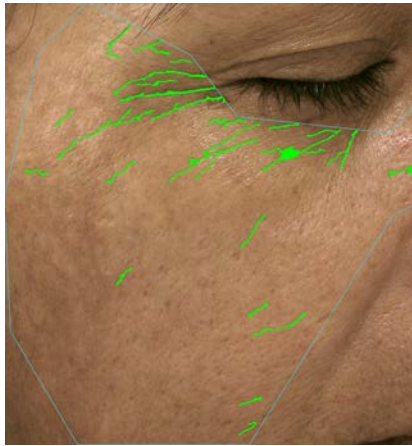
Before



After



Before



After



Before



After