EVALUATION OF TOPICAL ANTI-WRINKLE AND FIRMING (AWF) FOR WOMEN, ANTI-WRINKLE AND FIRMING (AFM) FOR MEN AND DEEP WRINKLES FOR WRINKLES ON FACE AND NECK

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ABSTRACT
Wrinkles are the clinical manifestation of ‘cutaneous aging’ and factors associated with wrinkles could be ‘intrinsic’ and ‘extrinsic’. [1] Intrinsic skin aging is determined largely by genetics and occurs in spite of the individual’s environment. Clinically, intrinsic skin aging manifests by signs such as increased dryness, wrinkles, and skin thinning. Photoaging is the superposition of chronic ultraviolet (UV)-induced damage on intrinsic aging and accounts for most age-associated changes in skin appearance. [2] Manifestations of photoaging include superficial and deep wrinkles, development of a leathery texture, skin roughness, atrophy and dyspigmentation.

Extrinsic skin aging primarily arises from UV-light exposure. Approximately 80% of facial skin aging is attributed to UV-exposure.[3] Most of the photoaging effects occur by age 20. The amount of damage to the skin caused by the sun is determined by the total amount of radiation exposure and the person’s pigmentation protection. Changes in the epidermis caused by the sun include thinning of the epidermis and expression of epidermal lesions such as actinic keratoses, basal cell carcinomas, and squamous cell carcinomas. In the dermis, solar effects cause collagen to break down to a higher rate than seen with just chronologic aging. The dermis and hypodermis become atrophied during aging, with a reduction of collagen,[4,5] of certain glycosaminoglycans (GAG)[6-9] and of the adipose tissue of the hypodermis.[4,10] These reductions lead to wrinkle formation. On the otherhand, elastic tissue hypertrophy produces huge amounts of elasticotastic material, which increases the magnitude of the wrinkles.[4,5,11-13] With the advent of solar elastosis matrix metalloproteinases are produced in large quantities.

The most critical step in the treatment of wrinkles is sun avoidance and sunscreen use. Prevention and progression of wrinkles can be achieved by usage of a broad spectrum sunscreen regularly, about 20 to 30 minutes before sun exposure in addition to maintaining the moisture balance of the skin.

Cosmetic active molecules from various sources with complementary biological properties for optimum effectiveness for effective management of wrinkles are a current trend in antiaging. With recent advances in pathophysiologic understanding of aging processes we know that hormonal profile, oxidative stress and inflammatory insults are major contributors. According to the free radical theory of aging, reactive oxygen species (ROS), primarily arising from oxidative cell metabolism, play a major role in both chronological aging and Photoaging [14] Oxidative stress and inflammation in the skin can result from both normal and pathological reactions and whatever the cause, both the process has a big influence on skin aging. There are effective ways of modulating these mechanisms with a combination of selected commercially available actives formulated in a serum. The cosmetic active molecules are derived from vegetable, marine, peptides, and biotechnological sources with complementary biological properties for optimum effectiveness for effective management of wrinkles.

INTRODUCTION
Wrinkles are the clinical manifestation of ‘cutaneous aging’ and factors associated with wrinkles could be ‘intrinsic’ and ‘extrinsic’. [1] Intrinsic skin aging is determined largely by genetics and occurs in spite of the individual’s environment. Clinically, intrinsic skin aging manifests by signs such as increased dryness, wrinkles, and skin thinning. Photoaging is the superposition of chronic ultraviolet (UV)-induced damage on intrinsic aging and accounts for most age-associated changes in skin appearance. [2] Manifestations of photoaging include superficial and deep wrinkles, development of a leathery texture, skin roughness, atrophy and dyspigmentation.

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to Regen 16 Technology, the following additional ingredients namely Neutrazen, PhytoCell Tec Alp Rose, Skin Influx, Snap B C, Vivendin, Willow Bark, Co-enzyme Q10 and Retinol. Studies have shown that its use visibly reduces the appearance of wrinkles and fine lines, improves tone for firmer skin, lightens pores for smoother looking skin and lightens the complexion for more luminous & radiant look.

‘Anti-Wrinkle and Firming (AFM) for Men’ is an Integral Correction Serum that is specifically formulated for male skin addressing the anatomical and physiological differences found between male and female skin. It contains in addition to Regen 16 Technology, the following additional ingredients Juvinity, Orsirtine GL, PhytoCellTec Alp Rose, and Vivendin. Studies have shown that its use maintains and prolongs the firmness, tightness and structure of male skin.

‘Deep Wrinkles’ is an Integral Correction Serum that significantly reduces the appearance of deep wrinkles. In addition to Regen 16 Technology contains following additional ingredients Guanidine complex, Lapinol, PhytoCellTec Alp Rose, Tegopep-17, and Retinol cyclosystem complex.

This integrated approach to skin ageing and appearance of wrinkles was tested in Indian patients by conducting a clinical study to determine the efficacy and safety of topical ‘Anti-Wrinkle and Firming (AWF) for Women’, ‘Anti-Wrinkle and Firming (AFM) for Men’ and ‘Deep Wrinkles’ in the treatment of wrinkles in face and neck. The aim of the study was to assess the efficacy, safety and quality of life parameters after treatment with anti-wrinkle and firming in patients with wrinkles on face and neck.

**Study Design**

This was an open labelled, prospective, multi-centric study conducted in patients with wrinkles on face and neck. This was conducted in accordance to the ICH-GCP guidelines with approval from Independent Ethics Committee. Written Informed consent was obtained from these patients after a thorough explanation of the study.

Patients with wrinkles on the face and neck were included in the study. These patients agreed to refrain from prolonged exposure to the sun for the length of the study. Patients were excluded from the study if they had any history of hypersensitivity to any ingredients, were pregnant or lactating women, already applying any anti-wrinkle products (if any), as Average (Grade 1), Good (Grade 2), Very Good (Grade 3) and Excellent (Grade 4) on Visit 2 and 3.

**Physician’s and Patient’s Global Assessment Grade for improvement in wrinkles were graded as Grade 0: Worse; Grade 1: No Change; Grade 2: Slightly Improved; Grade 3: Improved; Grade 4: Much Improved.**

**RESULTS**

Thirty patients with fine to deep wrinkles were included in the study with 10 patients each Anti-Wrinkle And Firming (AFM) for Women and Anti-Wrinkle And Firming (AFM) for Men or Deep Wrinkles (DW), who completed 12 weeks of therapy.

**Results - Anti-Wrinkle and Firming (AFW) for Women**

The average MFWS (Modified Fitzpatrick Wrinkle Scale) at baseline (Visit 1) was 1.8 which was reduced to 1.4 after 6 weeks of treatment (Visit 2) and further reduced to 1.1 after 12 weeks of treatment (Visit 3), as shown in figure 1.

**Figure 1:** Average MFWS score at Visit 1 (Basal), Visit 2 and Visit 3

The Physician’s and Patient’s global assessment showed improvement in wrinkles at visit 2 and visit 3, as shown in figure 2. Average grade for Physician’s global assessment improved from 1 at baseline to 2.1 at the end of 12 weeks treatment. Patient’s global assessment also showed similar grades of improved from 1 at baseline to 2 at the end of treatment.
Figure 2: Physician and Patient global assessment at each visit

There was an overall improvement in ‘Quality of Life’ in terms of improvement in the wrinkles at the end of 6 weeks (Grade 2.6) and 12 weeks (Grade 2.9), as shown in figure 3. All the patients responded that they would like to continue the treatment and would recommend the treatment to others. The overall ‘Patient Satisfaction’ was found to be good at the end of 6 weeks (Grade 2) and 12 weeks of treatment (Grade 2.5), as shown in figure 3.

Figure 3: Quality of Life & Patient Satisfaction Questionnaire at Visit 2 and Visit 3

Figure 4: photographic assessment for Anti-Wrinkle and firming (AWF) for Women at Visit 1, Visit 2 and Visit 3

Results - Anti-Wrinkle and Firming (AFM) for Men

The average MFWS (Modified Fitzpatrick Wrinkle Scale) at baseline (Visit 1) was 2.1 which was reduced to 2 after 6 weeks of treatment (Visit 2) and further reduced to 1.6 after 12 weeks of treatment (Visit 3), as shown in figure 4.

Figure 4: Average MFWS score at Visit 1(Basal), Visit 2 and Visit 3

The Physician’s and Patient’s global assessment showed improvement in wrinkles at visit 2 and visit 3, as shown in figure 5. Average grade for Physician’s global assessment improved from 1 at baseline to 2.6 at the end of 12 weeks treatment. Patient’s global assessment also showed similar grades of improved from 1 at baseline to 2.7 at the end of treatment.

Figure 5: Physician and Patient global assessment at each visit

There was an overall improvement in ‘Quality of Life’ in terms of improvement in the wrinkles at the end of 6 weeks (Grade 2.5) and 12 weeks (Grade 2.9), as shown in figure 6. All the patients responded that they would like to continue the treatment and would recommend the treatment to others. The overall ‘Patient Satisfaction’ was found to be good at the end of 6 weeks (Grade 2) and 12 weeks of treatment (Grade 2.5), as shown in figure 6.

Figure 6: Quality of Life & Patient Satisfaction Questionnaire at Visit 2 and Visit 3

Figure 7: photographic assessment for Anti-Wrinkle and Firming (AFM) for Men at Visit 1, Visit 2 and Visit 3

One patient for Anti-Wrinkle and Firming (AFM) for Men dropped out of study due to adverse event.

Results - Deep Wrinkles

The average MFWS (Modified Fitzpatrick Wrinkle Scale) at baseline (Visit 1) was 2.7 which was reduced to 2.6 after 6 weeks of treatment (Visit 2) and further reduced to 2.1 after 12 weeks of treatment (Visit 3), as shown in figure 8.

Figure 8: Average MFWS score at Visit 1(Basal), Visit 2and Visit 3

The Physician’s and Patient’s global assessment showed improvement in wrinkles at visit 2 and visit 3, as shown in figure 9. Average grade for Physician’s global assessment improved from 1 at baseline to 2.7 at the end of 12 weeks treatment. While Patient’s
global assessment also showed grades of improved from 1 at baseline to 2.2 at the end of treatment.

Figure 9: Physician and Patient global assessment at each visit
There was an overall improvement in ‘Quality of Life’ in terms of improvement in the wrinkles at the end of 6 weeks (Grade 2.3) and 12 weeks (Grade 2.7), as shown in figure 10. All the patients responded that they would like to continue the treatment and would recommend the treatment to others. The overall ‘Patient Satisfaction’ was found to be good at the end of 6 weeks (Grade 2.1) and 12 weeks of treatment (Grade 2.5), as shown in figure 10.

Figure 10: Quality of Life & Patient Satisfaction Questionnaire at Visit 2 and Visit 3
Two patients in Deep Wrinkles (DW) group were lost in follow-up.

Assessment of Adverse Events
Of the thirty patients, one patient for Anti-Wrinkle and Firming (AWF) for Women complained of acne form eruptions and the one patient complained of burning sensation. One patient of Anti-Wrinkle and Firming (AFM) for Men showed papules on hair line and other patient was dropped out of study due to extreme irritation and dryness. Two patients on Deep Wrinkle therapy showed burning and tingling sensation.

DISCUSSION
The recent introductions of Anti-Wrinkle and Firming (AWF) for Women, Anti-Wrinkle and Firming (AFM) for Men and Deep Wrinkles (DW) are a new therapeutic approach in the management of photoaging. All these three formulation contains active ingredient base with Regen-16 produced through patented technology. Regen 16 is a combination of 16 different ingredients along with other active agents targeting various probable causes of photoaging. 15

A preliminary study was conducted by independent testing laboratory to evaluate anti wrinkle potential of the serum. The results demonstrated that the integral approach improved the appearance of fine lines and wrinkle as well as the tone, texture, consistency and general appearance of the skin of 20 women aged 35-62 years. 15

In our study it was noted that, Anti-Wrinkle and Firming (AWF) for Women or Anti-Wrinkle and Firming (AFM) for Men or Deep Wrinkles (DW) appears to be effective and safer alternative with 3 months of therapy. In terms of efficacy, there was a mild to moderate reduction in the MFWS score for the treatment groups, brought about with 12 weeks of treatment.

One of the reason for Anti-Wrinkle And Firming (AWF) for Women or Anti-Wrinkle And Firming (AFM) for Men or Deep Wrinkles (DW) showing better results could be due to use of various combination of ingredients for an extended spectrum of activity interfering with the different steps of photoaging. The association of various ingredients with different mechanisms of action appears to be a useful strategy to improve clinical efficacy, and the risk of adverse effects as in the present study.

CONCLUSION
Great advances have been made to understand photoaging and the processes underlying photoaging in the last decade. The trend toward integration of multiple actives covering all mechanic aspects of skin ageing process. This research has led to development of safer and more effective anti-aging products. The results of this study show that Anti-Wrinkle and Firming (AWF) for Women, Anti-Wrinkle and Firming (AFM) for Men and Deep Wrinkles (DW) have a good potential for treatment of wrinkles. The better results could be because of targeting different steps of photoaging which improves clinical efficacy with better safety profile.

REFERENCES


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