Protocol of biorevitalization with Sodium Hyaluronate 45mg/3mL in association with amino acids, polyphenols, and antioxidants.

AUTORS: PhD Philippe Deprez (1), Dra. Inma González (2), Dra. Evgeniya Ranneva (3).

CENTERS: (1, 3) Clinica Hera, Empuriabrava, España. (2) Centro Integrativo de Salud CiSIG, Barcelona, España.

COLLABORATORS: Dra. Anca Radukan, MD (Clínica de Dermatología ALYRA medica, Romania); Gulsen Akoglu, PhD in dermatovenereology, MSc in Immunology (University of Health Sciences Ankara Gulhane School of Medicine, Ankara, Turkey); Asuman Caylar, MD (UNIVERSAL MEDICAL CLINIC, Alanya/Antalya/Turkey, Banu Kaya, MD, Odemis State Hospital, Izmir, Turkey).

INTRODUCTION

Application of dermal implants for biorevitalization containing Hyaluronic Acid (HA) corrects the signs of skin aging and dermal atrophy by restoring hydration and normal skin physiology. Depending on the degree of skin photoaging and its condition, HA can provide satisfactory results both as a single treatment

and/or as one of the stages of a treatment. The objective of the study is to evaluate the efficacy achieved in the improvement of patients with various degrees of skin photoaging, as well as to evaluate their degree of satisfaction during the international multicenter study with 51 patients involved.

ACTIVE AGENTS

3 ml pre-filled syringe with non-cross-linked HA (concentration of 15 mg/ ml) combined with a protective buffer containing antioxidant properties including amino acids (Glycine, Leucine, Lysine HCl, Proline, Alanine, Arginine Aspartate, Histidine, Isoleucine, Glutamine, Serine, Valine, Threonine, Phenylalanine, Tyrosine), polyphenols (Vitis Vinifera Vine Extract) and antioxidants (Taurine, Resveratrol).

INJECTION TECHNIQUE

Injection with a 30G or 32G needle and a luer lock syringe, leaving papules on the skin resting on the retention ligaments. Volume per session: 1.5 ml side / 3.0 ml for the full face.

PROTOCOL

Day 0. Treatment 1.

- **1.** Selection of the patient according to the general condition of the skin.
- Examination of the skin according to certain parameters (texture, thickness, skin type, turgor, flaccidity, general condition).
 Selection of the technique to be used and injection points for each patient considering the full-face treatment and total injection volume of 3 ml.
- **4.** Monitoring of adverse events during and after the treatment.
- **5.** Taking pictures.

Day 14. Treatment 2.

- 1. Monitoring of adverse effects.
- 2. Taking pictures.

VOLUME PER SIDE

Day 21. Control visit.

- 1. Evaluation of results through numerical satisfaction scales filled in according to doctor and patient responses.
- **2.** Examination of the skin according to the following parameters: texture, thickness, skin type, turgor, flaccidity and general condition.

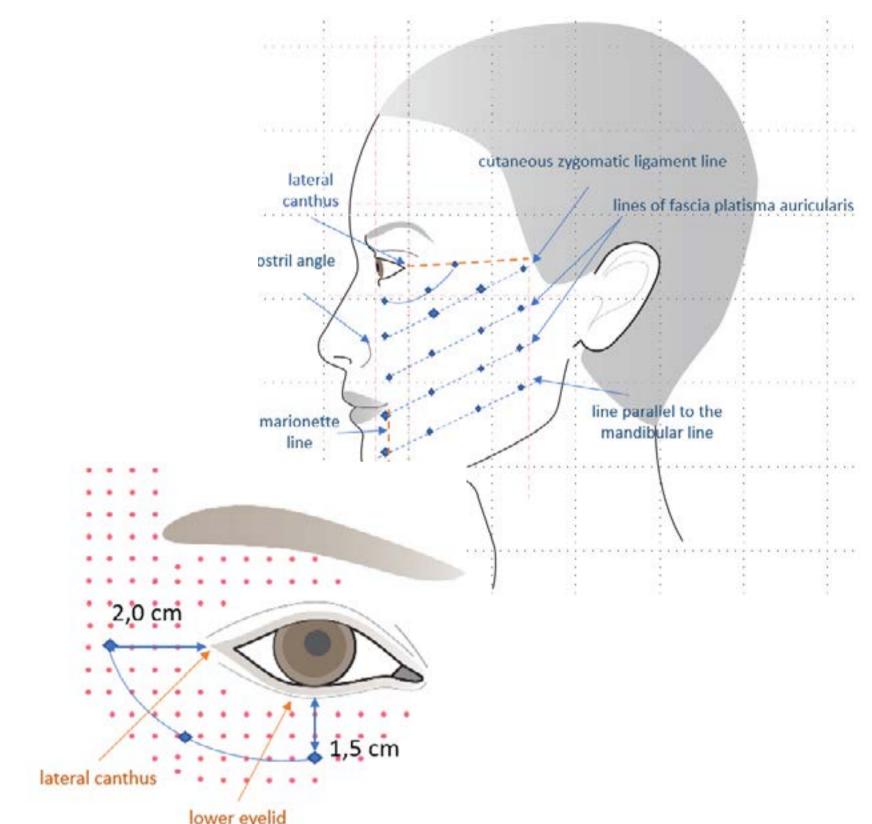
INJECTION MAP:

RRS® Hyalift® 75 Proactive

3. Monitoring of adverse events.

INJECTION DEVICE	30G/32G needle
INJECITON DEPTH	Intradermal
VOLUME PER POINT	0.05 – 0.1 mL

1.5 mL



METHOD

The biorevitalizing solution is applied transdermally, making papules at points of maximum tension in areas of retention ligaments or false ligaments.

The solution is injected with 30 or 32 G needles and luer lock syringes, leaving papules on the skin resting on the retaining ligaments. Two separate sessions are carried out 2 weeks apart, carrying out the control one week after the last application. In each session, 1.5 ml is injected on each side of the face, administering 0.05-0.1 ml of solution per point. For the evaluation of results, numerical scales from 0 to 10 were used for parameters of safety, efficacy, ease of use, local effects of application. Both doctors and patients gave their responses.

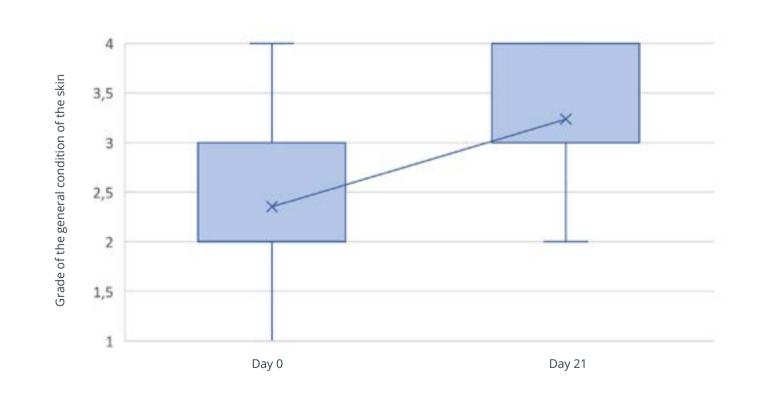
SAFETY RESULTS

No allergic reactions or systemic adverse reactions have been detected. The product displays good local tolerability.

INVESTIGATOR EVALUATION RESULTS

1. Evaluation of the general condition of the skin

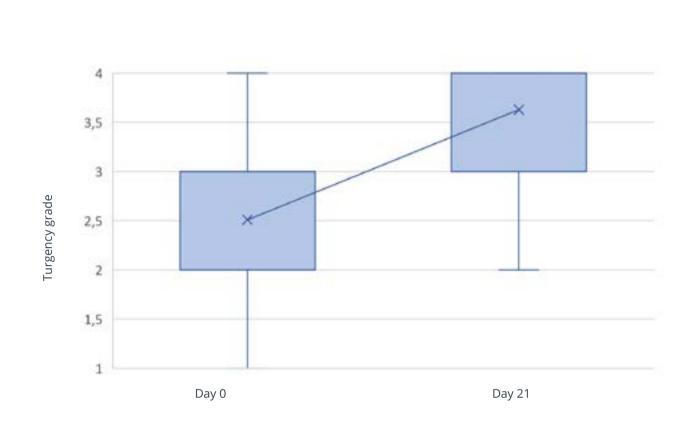
Increase in the parameter of the general condition of the skin by the descriptive visual scale, from 2.35 (ranging from 1 to 4) be-



fore treatment to a mean grade of 3.24 (ranging from 2 to 4) on day 21 has been observed.

* The grades were distributed as follows: 4 – very good, 3 – good, 2 – moderate, 1 – bad.

2.Evaluation of skin turgor



Significant increase in the turgor parameter according to the descriptive visual scale, from an average grade of 2.50 (varying from 1 to 4) before treatment to an average grade of 3.62 (with a variation from 2 to 4) on the day 21.

* The grades were distributed as follows: 4 – very good, 3 – good, 2 – moderate, 1 – bad.

3. Physician satisfaction with skin condition: 100% of investigators rated product efficacy and its adherence to expectation as excellent (82%) and good (18%).

PATIENT ASSESSMENT RESULTS

1. Evaluation of compliance with expectations of the patient: 90% of patients evaluated compliance with their expectations and efficacy of the product as excellent (76%) and good (14%).

2. Patient satisfaction with skin condition: 98% of patients reported skin condition after treatment as excellent (76%) and good (22%).

* The numerical evaluation scale applied to both evaluations: 0-2 – no effect, 3-4 – poor, 5-6 – average, 7-8 – good, 9-10 – excellent.

CONCLUSIONS

- **1.** HA based mesotherapy together with the biorevitalizing solution with amino acids, polyphenols, and antioxidants (RRS® Hyalift® 75 Proactive) is indicated for people with an incipient or advanced degree of chrono and photoaging of the skin.
- 2. The result is the hydration and restructuring of the dermis, improved laxity, thickness, and elasticity as well as improved external signs of skin aging.
- **3.** The application of Sodium Hyaluronate 45 mg/3 ml is an important step prior to treatment with Botulinum Toxin, Fillers or APL to improve the skin condition in patients with aging type III or IV according to the scale of Glogau.
- **4.** In patients with type I or II, it is a treatment that provides satisfactory results by itself, such as the one carried out in this study.
- * The author of this poster declares that he has no conflict of interest regarding the product undergoing the study.

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Clinical case 1. 48-year-old patient Centro Integrativo de Salud, Barcelona, España. Dra Inma González.



Clinical case 2. 48-year-old patient Centro Integrativo de Salud, Barcelona, España. Dra Inma González.





Clinical case 3. 47-year-old patient Clínica de Dermatología ALYRA medical. Dra Anca Raducan.