

TEOSYAL Redensity [I]

LIGHT FILLING™

Redensification of the dermis

Composition:

- Non cross-linked Hyaluronic Acid at 15mg/g
- Dermo-Restructuring Complex (Supplemented phosphate buffer)
- Lidocaine 0,3%

Blister pack: 2 x 1 ml - 1 x 3 ml

Indications: Hydratation, radiance, elasticity, wrinkles and fine lines

Treated areas: Face / Neck / Neckline

Injection site: Reticular Dermis

Protocol: 3 sessions at 3 weeks intervals

Top up session: 2 to 3 sessions per year according to the skin's condition

REFERENCES

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(7) Nicolas Atrux-Tallau, Ngoc T.T Huynh, Laurie Gardette, Cyril Paillet-Mattéi, Hassan Zahouni, Eric Viviant, Henri Hirsch, Haftek Marek, Françoise Falson, Fabrice Pirov
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TEOSYAL® Redensity [I],
a new light reflecting treatment

A multicentric and international clinical study of a new non cross-linked
hyaluronic acid gel

THE BEST OF HYALURONIC ACID

TEOSYAL

EFFECTIVE • SAFE • LONG-LASTING

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TEOSYAL® Redensity [I], a new light reflecting treatment

A multicentric and international clinical study of a new non cross-linked hyaluronic acid gel
B. Knoll, Munich (Germany) - J. Vivier, Paris (France) - J. Carré, Paris (France) - H. S. Padey, Cannes (France)

BACKGROUND

With ageing, the skin becomes dryer and loses elasticity and tonicity. In order to fight against this natural process and to improve the quality of the skin, Teoxane Laboratories, specialized in Aesthetic Dermatology, have formulated an innovative injectable medical device made of non cross-linked hyaluronic acid (HA) based gel, supplemented with a Dermo-Restructuring Complex (including vitamin, amino acid and antioxidant factors).

OBJECTIVE

The objectives of this study were to evaluate the efficacy and safety of this new non cross-linked hyaluronic acid based gel in the treatment of the skin, comparing different injection techniques, in the face, neck and neckline, as follows:

1. **Evaluation of the efficacy of Teosyal® Redensity [I]**, based on a 3 injection sessions treatment, with 3 weeks of intervals, whatever the technique
2. **Safety of the treatment**, depending on the injection technique used
3. **Long-lasting of the treatment** at the different visits
4. **Patient satisfaction**
5. **Practitioner satisfaction**

PRODUCT

The product used in this study was Teosyal® Redensity [I], a transparent, apyrogenic, sterile, reticulated, hyaluronic acid, visco-elastic gel of non-animal origin, with a HA concentration of 15mg/g. This product is supplemented with a Dermo-Restructuring Complex (including vitamin, amino acid and antioxidant factors) and lidocaine. This Dermo-Restructuring Complex brings to Teosyal® Redensity [I] gel additional properties, as nutritive action for skin cells, and protective action against cellular oxidation responsible of skin aging process.

METHODOLOGY

■ TARGET POPULATION

Male or Female patients, aged of 35 to 55 years old, showing wrinkles and thine wrinkles at the level of face, neck and neckline, with a WSRS grade of 2 to 3.

■ STUDY DESIGN AND PROCEDURE

Ninety (90) patients in total have been treated at the level of the face, neck, and/or neckline areas. The treatment is based on a 3 injection sessions protocol with 3 weeks of intervals between each injection session: Visit 1/Week 0 (first injection), Visit 2/Week 3 (second injection), Visit 3/Week 6 (third injection) and a last study visit (Visit 4) was performed during Week 9 for an end of study control visit 3 weeks after the last injection session. The efficacy assessment was performed through qualitative evaluation scales of the skin using the **Global Aesthetic Improvement Scale (GAIS)**, a quantitative evaluation of the skin measured with **Intuiskin medical device** and before and after pictures performed with **Quantificare 2D DermaViz**. The safety was assessed through the reporting of side effects just after injection and during the following visits.

INJECTION TECHNIQUES

In this study three techniques of injection were used:

■ MULTI-PUNCTURE Technique (Dr Knoll):

Multiple injections of small quantities of product are injected into the epidermis. The injection points are very close together and distributed evenly across the area to be treated or form a line along the length of the wrinkle. Here, the injections were performed with an injection pen. This type of injection minimizes the immediate inconveniences inherent to injections and brings to the skin hydration and revitalization.

■ MULTI-BOLUS Technique (Dr Vivier and Dr Carré):

Multiple and manual injections were made point by point (called bolus). A small amount of product of no more than 0.05ml is injected in the superficial to the mid dermis with 1 cm apart. These small papules usually disappeared within 24 to 48 hours following injection. This technique is usually recommended for mature skins and brings to the skin deep hydration.

■ RETROGRADE Technique (Dr Padey):

Injections into the mid dermis, using a linear technique that consists of inserting the needle at an angle of 45°, along the cutaneous depression, then depositing the product in the mid dermis while removing the needle gently.

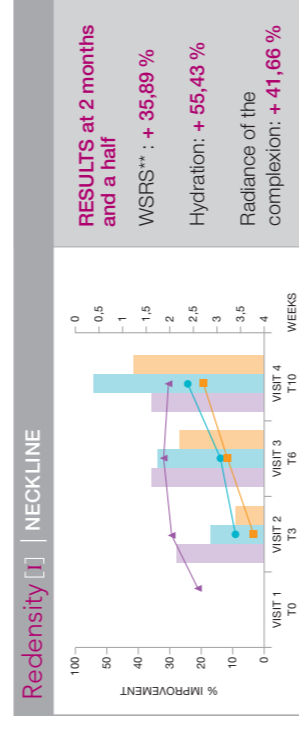
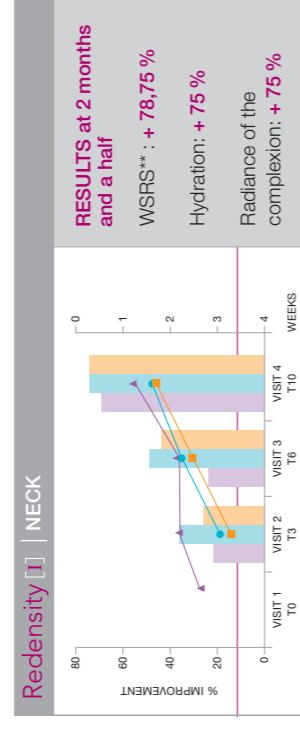
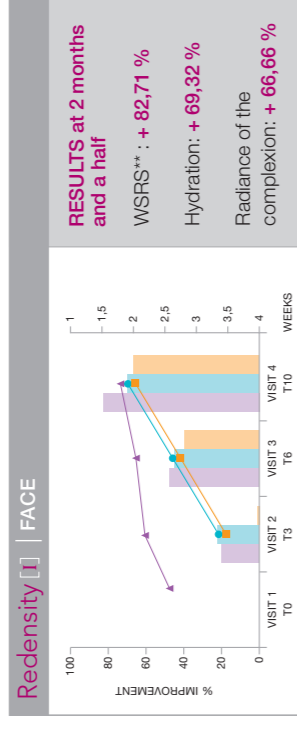
CONCLUSION

This study clearly demonstrated the benefits of using a new generation of non cross-linked hyaluronic acid gel including a Dermo-Restructuring Complex and lidocaine, in the treatment of young and mature skins for hydration and revitalization, with only few and transitory adverse events.

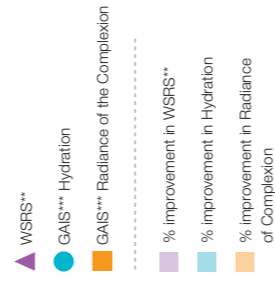
The features appear smoother and the skin is redensified. The face looks younger with more healthy and lightened skin.

- 92.7% of patients are satisfied with the treatment,
- 92.7% of patients are ready to be treated again with the same protocol,
- 90.2% of patients would recommend the treatment.

OUTCOMES EFFICACY



**WSRS Grade: evaluates the degree of severity of patients' wrinkles
***GAIS Grade: overall aesthetic improvement scale

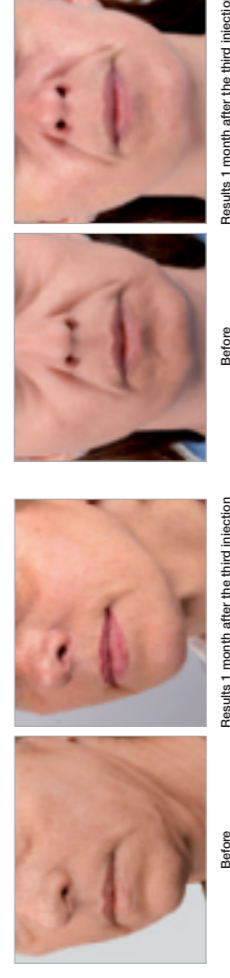


VISIT 1
Measurements taken before the first session
VISIT 2
Measurements taken three weeks after the first session
VISIT 3
Measurements taken three weeks after the second session
VISIT 4
Measurements taken 1 month after the third session

Outcomes for efficacy show a great improvement of the skin in the three areas treated: face, neck and neckline, regarding hydration, wrinkle depth, and radiance of the complexion. At each visit, measurements and photographs were performed before each injection.



Scientific results provided with SkinEvidence™ medical device measuring for each patient each visit the following parameters: anisotropy, hydration, TEWL and Temperature.



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SAFETY

The tolerance of the product is very high with 69% of patients who did not report any side effect at all. 26% of patients reported transitory side effects as redness, and 5% slight hematomas. No serious adverse event reported.

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