

 SWISS INNOVATION APPLIED TO WRINKLES

Prospective study assessing the tolerance of TEOSYAL Deep Lines in the correction of nasogenian fold, as well as its clinical efficiency

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Ethical approval for the study obtained from the Cardiff Independent Research Ethics Review Committee



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Hyaluronic acid (HA) dermal filler are commonly used to reduce" facial lines and wrinkles. After an injection of HA, there is normally a mild inflammatory reaction. This can vary in intensity and duration according to the dermal filler used, injection techniques and the individual response of the subject. This study was designed to assess the intensity and duration of the inflammation following a single injection of Teosyal Deep Lines in volunteer subjects.

Objectives

- **The primary objective** of the study is to determine the intensity and duration of the inflammation induced by an injection of Teosyal Deep Lines in the nasogenian folds using objective and subjective means.
- **The secondary objective** is to evaluate the good tolerance and the clinical efficiency of Teosyal Deep Lines.

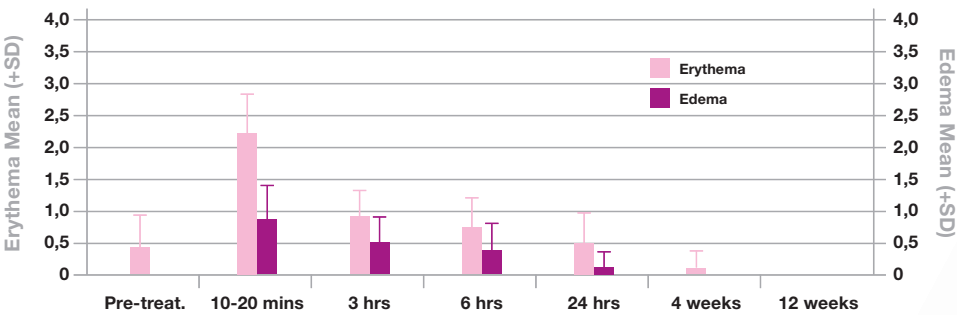
Material and methodology

- Prospective clinical study in 25 volunteers whose mean age of subjects taking part was 46 years old.
- The study was open and all subjects received a single injection of Teosyal Deep Lines in the nasogenian folds left and right (average volume injected: 0.83 ml in each nasogenian fold).
- The presence of erythema and edema in the nasogenian folds was clinically evaluated by the dermatologist (Harryono Judodihardjo).
- The objective measure of erythema was made by a Mexameter.
- The skin surface temperature measurement was realized through an infrared thermometer.
- Before the treatment, 24 hours, then 12 weeks after the treatment, wrinkles of the nasogenian folds were clinically measured according to WSRS (Wrinkle Severity Rating Scale).
- The subject discomfort was assessed by VAS (Visual Analog Scale).
- 12 weeks after the injection, a clinical examination was made to determine overall aesthetic improvement using the GAIS (Global Aesthetic Improvement Scale).
- No treatment with topical anesthetic cream.

Results

Measurement of erythema and oedema after injection:

(Clinical assessment by the dermatologist)



Erythema:

- Mild irritation at 10 – 20 minutes after the injection.
- At 3 hours, the mean erythema score was much reduced.
- At 24 hours, the score was comparable to pre-treatment values.

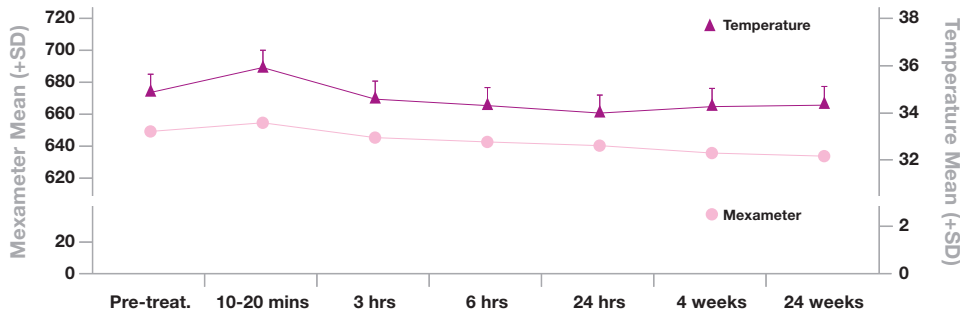
Oedema:

- Mild increase at 10 – 20 minutes after the injection.
- Disappearance of the oedema 24 hours after the injection.



Measurement of inflammation after injection:

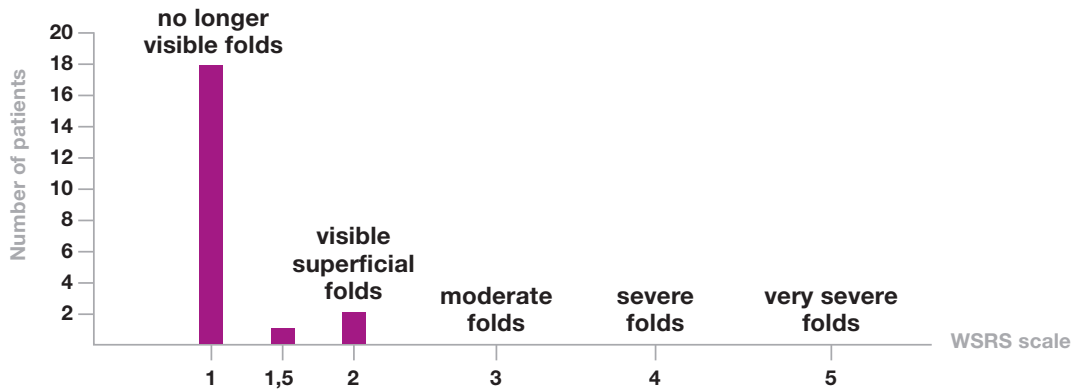
(Assessment by a Mexameter and an infrared cutaneous thermometer)



- Three hours after the injection, means values were back to initial score.
- The observed cutaneous inflammation was very short-lived.

Measurement of the clinical efficiency:

(Assessment using WSRS scale at 12 weeks after the injection)



- After a single injection and without a touch-up session, we observe an immediate and visible correction of the wrinkle that disappears completely in 84% of cases.
- Results unchanged 3 months after the injection.

Measurement of subject discomfort after injection:

(Assessment using VAS scale)

- Mild discomfort at 10-20 minutes after the injection.
- The discomfort has disappeared after 3 hours.

Measurement of patient satisfaction¹ :

(Assessment using GAIS scale 12 weeks after the injection)

- 77% of patients observed a very significant correction of the depth of their wrinkles. The others observed a significant correction.
- Answering the question “How long did it take to feel at ease in front of your relatives”, 91% of patients answered “the same day”.
- For 100% of patients, the result was natural after the injection.
- 100% of patients would recommend the treatment.

Conclusions

- The results of the study have shown that the intensity and degree of inflammation associated to Teosyal Deep Lines was minimal and transitory in nature.
- The observed cutaneous inflammation was shorter than those reported in several others studies.²
- No significant side-effects were reported during the study.
- The much shorter duration of inflammation observed can be due to the low level of protein residue in Teosyal Deep Lines.
- Study clearly showed the clinical efficiency of Teosyal Deep Lines in the correction of the wrinkles 3 months after the injection. However, European doctors' reports have suggested that the effect of the injection of Teosyal Deep Lines last 9 months in average.

Teosyal Deep Lines is a safe, efficient and well tolerated product for patients.

¹: Patients who answered the survey.

²: Micheels mentions a post-injection cutaneous inflammation of HA that could last 2 to 8 days. Micheels P. Human anti-hyaluronic acid antibodies: is it possible? Dermatol Surg 2001 ;27:185-91