

SUMMARY REPORT

CONTROLLED STUDY FOR CLINICAL AND INSTRUMENTAL EVALUATION OF BIO-REVITALIZING, SOOTHING AND RECONSTRUCTING EFFICACY OF AN INTRADERMAL INJECTABLE PRODUCT (JALU-PRO™) COMBINED TO CHEMICAL PEELING ON AGING FACE

Test code: PD0205

Study products:

- JALUPRO® (injectable vials for intradermal and intra-articular implant)
- Trichloroacetic acid in macromolecular gel (Canova Skin Care – SIFARMA S.p.A. – MILANO – ITALY)

Study Objective:

Aim of the study was to evaluate clinically and by non-invasive instrumental evaluations the bio-revitalizing and soothing efficacy on aging/photoaging skin signs of an intradermal injectable product combined to chemical peeling with TCA (trichloroacetic acid) 25%.

Study Design

Open trial conducted by 1 centre, under dermatological control for **6 months** of treatment.
2 different experimental groups were compared:

- **group I** (subjects performing chemical peeling and 5 intradermal implants with Jalu-Pro™);
- **group II** (subjects performing only chemical peeling);

Medical treatment plan

- **N°1** chemical peeling with TCA (trichloroacetic acid) 25%;
- **N°5** Intradermal implants with the injectable product "JALU-PRO™" only for subjects included in the group I.

The first implant (3 vials of lyophilised Jalu-Pro™, every dissolved in 1,5 ml of Jalu-Pro™ solvent) was performed 48 hours before the peeling, the following three (only 1 lyophilised Jalu-Pro™ vial dissolved in 2,5 ml of Jalu-Pro™ solvent) once a week and the last one 3 months after peeling.

Intradermal implants were performed by tunnelling technique using 26G needle on both face sides at level of the following skin areas:

- frontal region (third superior)
- periocular ("crow's feet") and malar region (third middle)
- nasolabial folds, chinlabial folds, mandibular region (third inferior).

Study Visit

The following visits were performed during the study period:

- baseline (T0 before peeling execution),
- the day of the first intradermal implant (T1 – only for the group I)
- the day of the peeling execution (TP –for the group I it was performed 48 hours after the first intradermal implant),
- 1, 2 and 3 weeks after peeling (T1W, T2W, T3W)
- 1, 3, and 6 months after peeling (T1M, T3M, T6M).

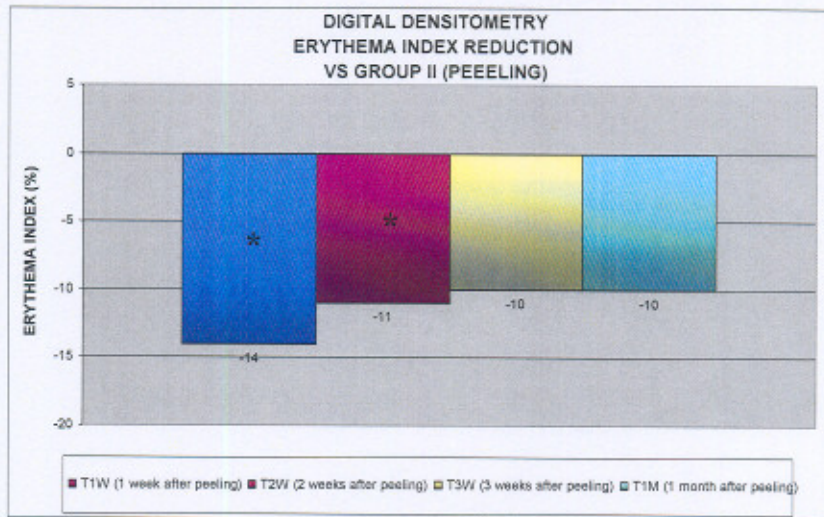
Study population:

20 healthy, female volunteers **aged more than 50 years, with severe skin ageing/photoaging** completed the study (10 subjects for each study group).

Results

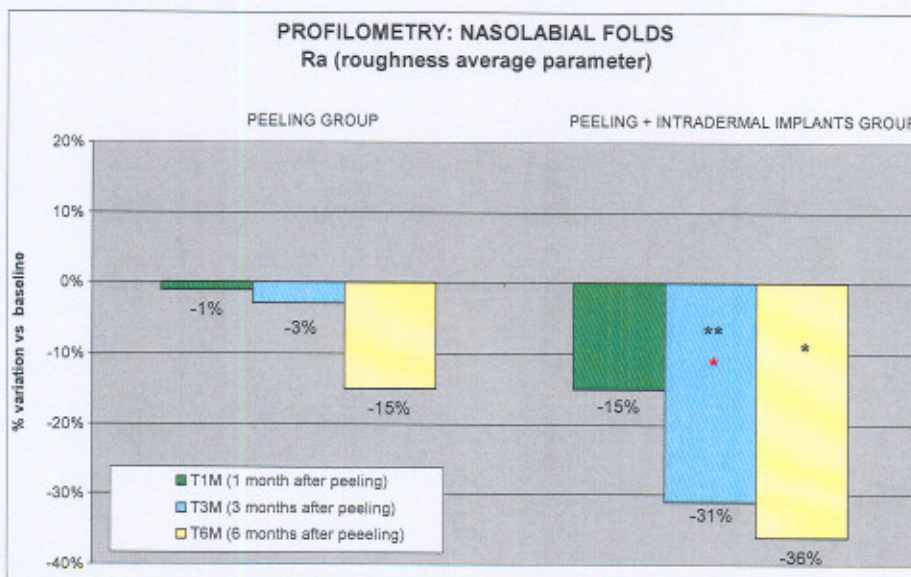
Clinical and instrumental study evaluations showed for the group I (peeling and the intradermal implants):

- a statistically significant reduction ($p < 0.05$ vs group II) of post-peeling erythema, determined by digital colorimetry, already 1 week after peeling, corresponding to 14% vs the group II (control group);



Statistical analysis: Student t test * $p < 0.05$ vs Group II (peeling)

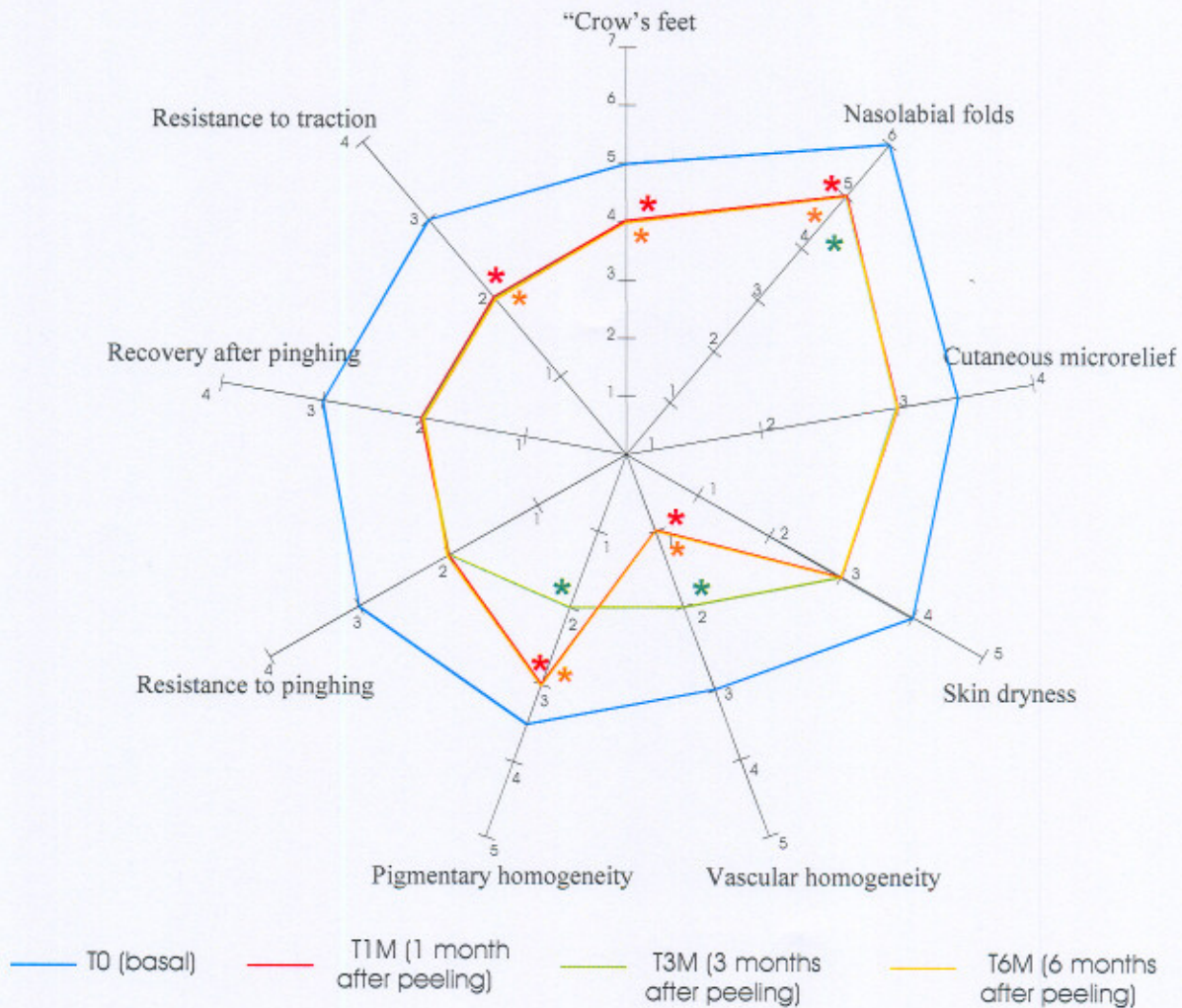
- a statistically significant reduction ($p < 0.05$ vs basal conditions) of nasolabial folds, determined by skin replicas image analysis, corresponding to a reduction of the profilometric parameter Ra (= arithmetic average roughness) of 31% at T3M and 36% at T6M;



Statistical analysis: Student t test * $p < 0.05$ and ** $p < 0.01$ vs basal conditions
* $p < 0.05$ vs T1M

- a clinically and statistically significant improvement of skin aging grade (visual score) evaluated by Spiderming® graph vs basal conditions (T0) of: nasolabial folds, wrinkles of the lateral corner of the eyes ("crow's feet"), skin tonicity/elasticity (resistant to pinching, recovery after pinching, resistance to traction at level of cheek-malaris region), of pigmentary and vascular homogeneity (at level of the cheek-malaris region by dermatoscopy).

**GROUP I (PEELING + INTRADERMAL IMPLANTS)
SKIN AGE GRADE EVALUATION (SPIDERMING®)**

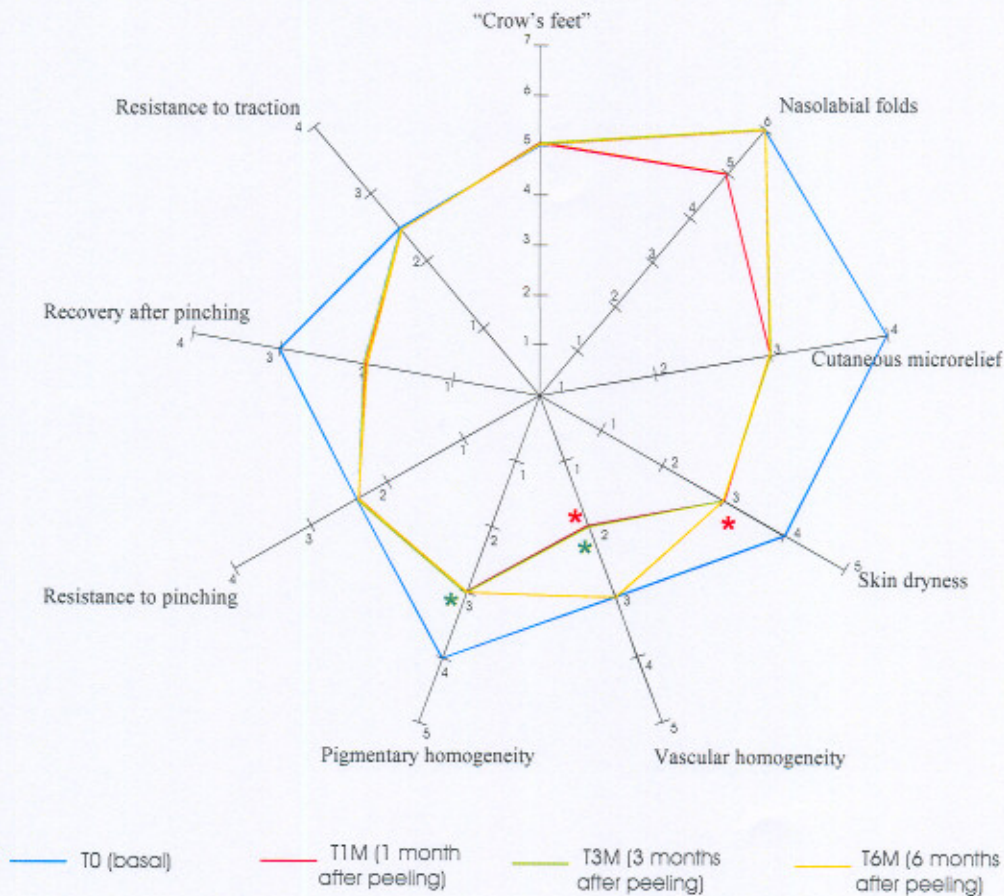


Statistical analysis: Dunnett test

- * statistically significant T1M vs T0
- * statistically significant T3M vs T0
- * statistically significant T6M vs T0

Comparison to the Spiderming® graph of group II (peeling) underlines as the activity of “Jalu-Pro™ injectable vial” combined to the TCA peeling regenerative stimulation on the principal aging/photoaging signs as wrinkles (nasolabial folds and at level of periorcular area), skin tonicity/elasticity (resistance to traction), vascular and pigmentary homogeneity is still present 6 months after peeling (see also photographic documentation).

GROUP II (PEELING) SKIN AGE GRADE EVALUATION (SPIDERMING®)



Statistical analysis: Dunnett test

* statistically significant T1M vs T0
* statistically significant T3M vs T0

Conclusions:

Clinical and instrumental study evaluations showed that:

- cutaneous regenerative processes induced by the TCA (25%) chemical peeling on principal skin aging/photoaging signs are strengthened by the metabolic activity of the injectable product under study, determining an important and clinically relevant improvement of skin tonicity/elasticity and of vascular homogeneity;
- the tested product determined in the treated subjects a statistically significant reduction of post-peeling skin erythema showing to have an important soothing activity.
- the excellent filling and bio-revitalizing efficacy over wrinkles and face folds of the injectable product "Jalu-Pro™" is still remarkable 6 months after peeling and intradermal injections.

These results are yet more interesting and clinically relevant, considering that the study population presented very consistent skin aging/photoaging signs of face,

Treatment tolerance was optimal; in fact no adverse event related to the study product(s) occurred during the entire study period.

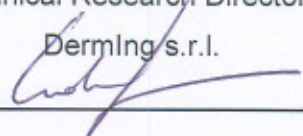
Date: 17th November 2006

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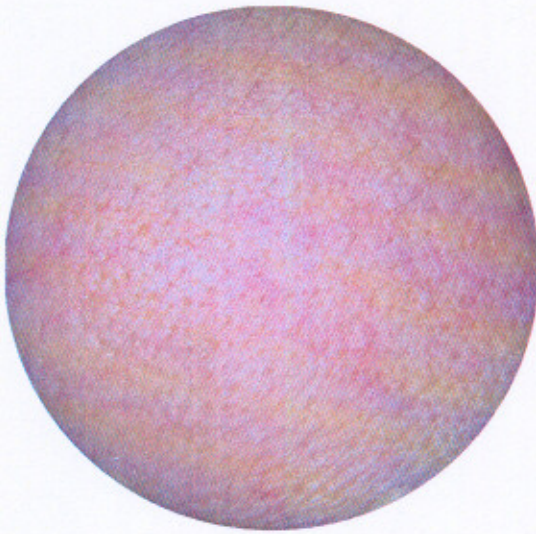
Dermatologist

Clinical Research Director

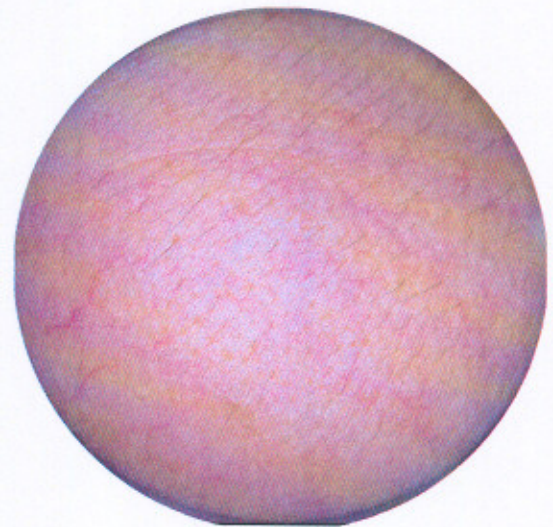
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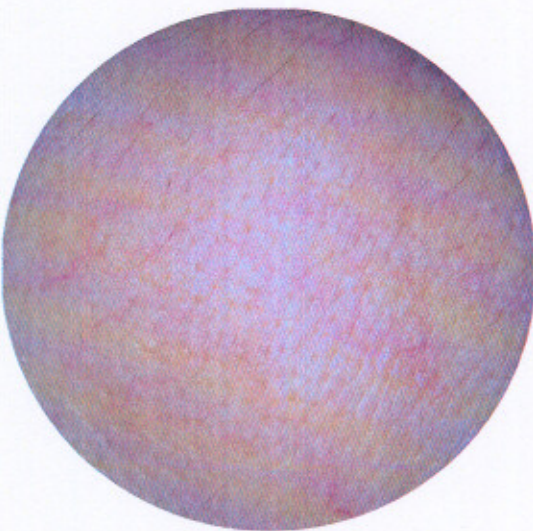
CUTANEOUS MICRORELIEF



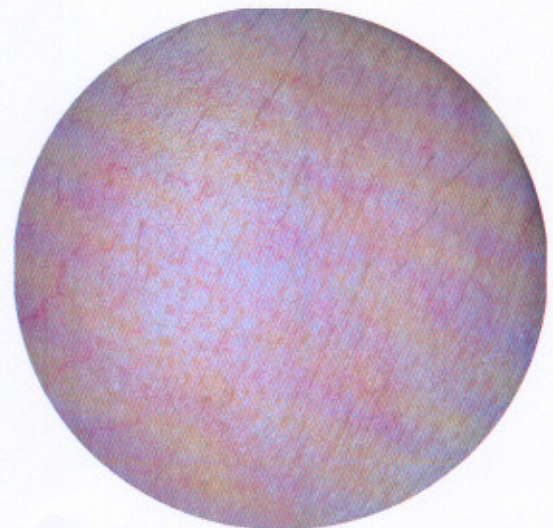
BASAL VISIT (T0)



T1 M
(1 month after peeling)



T3 M
(3 months after peeling)



T6 M
(6 months after peeling)

DermIng, Institute of Clinical Research and Bioengineering
Viale Cesare Battisti, 38 -20052 Monza (MI)
Tel.:039/329666 Fax: 039/5964228

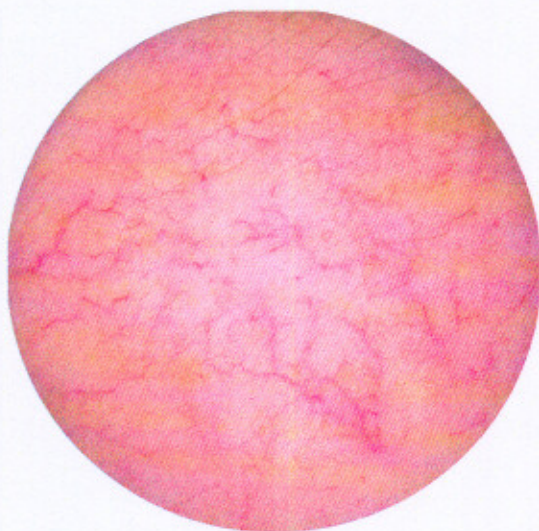


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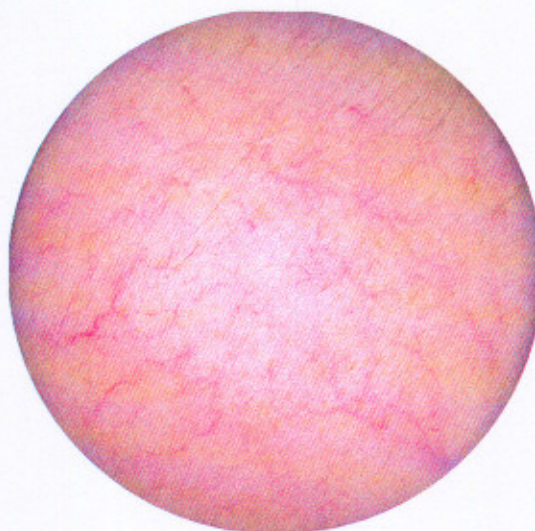
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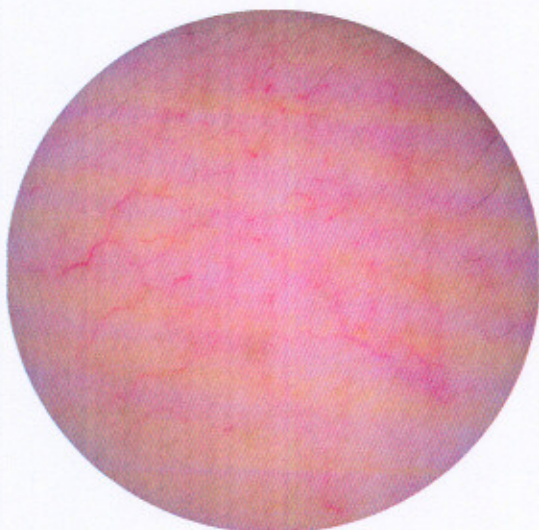
VASCULAR AND PIGMENTARY HOMOGENITY



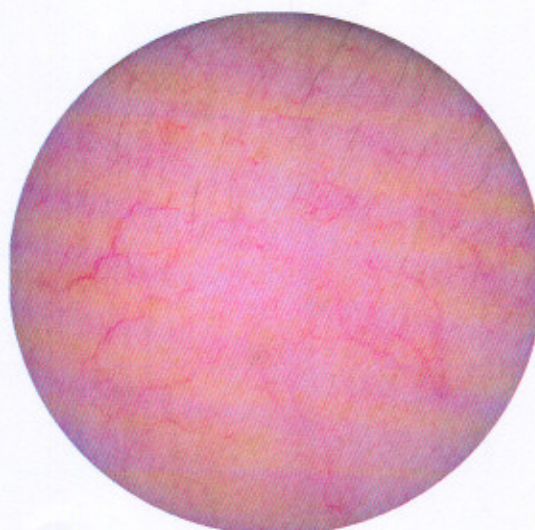
BASAL VISIT (T0)



T1 M
(1 month after peeling)



T3 M
(3 months after peeling)



T6 M
(6 months after peeling)

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