A NEW ANTI-WRINKLES COSMETIC SERUM. INSTRUMENTAL AND PHOTOGRAPHIC EVALUATION OF THE INSTANT LIFTING EFFECT.

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ABSTRACT

The immediate lifting effect of a new anti-wrinkle cosmetic serum (Instant Lifting) was evaluated with the application on the skin of the face (periorbital areas, lip contour) and on the back of the hands in 21 women and 3 men, 50-65 years old (average age: 58,3 years). Before and 5 minutes after product application, cutaneous replicas and digital photos of the treated areas have been executed.

The instrumental measurements showed that the product application induced after 5 minutes a significant decrease ($p<0.0001$) of the cutaneous roughness parameters, either for the Ra (mean roughness value) either for the Rz (maximum roughness value), at level of periorbital, lip contour and back of the hands wrinkles. The immediate lifting effect is also evidenced by a visible decrease of cutaneous roughness, clearly visible in the digital images.

A pilot test with another cosmetic serum, reference for the category, showed the superiority of the product Instant Lifting®. The related data are not reported because such comparative tests have been carried out on a limited number of subjects and intended as general orientation only.

All subjects testing Instant Lifting® declared a high level of satisfaction for the immediate and visible results. As a matter of compliance, samples of the product for personal use have been asked, after the end of the test, by all volunteers.

INTRODUCTION

Wrinkles are modifications of the skin associated with cutaneous ageing and develop in a more pronounced way on sun-exposed sites of the skin. Wrinkles represent only one aspect of the modifications of the skin surface linked with age.

There is debate concerning the anatomy and the histology of wrinkles but in permanent wrinkles anatomical changes occur in the epidermis (thin and flattened) and in the dermis (decrease in elastic fibers). The aspect and histology of the skin is deeply altered by chronic sun exposure, which causes epidermal atrophy, an increase in melanocytes numbers, accumulation of truncated elastic fibers (elastosis), decrease in collagen fibers and a dermal inflammatory infiltrate. Such histological modifications specific for the photo-damaged skin are always associated with wrinkles.

At present, different approaches are available

for anti-wrinkle treatments, the surgical intervention, the use of *Clostridium botulinum* and cosmetic treatments. Both the surgical lifting and the use of Botox not rarely expose the subjects to unwanted adverse events and to a more or less intense permanent loss of facial expressivity.

Cosmetic serums have often a moderate, if not a poor, anti-wrinkle effect, not immediately visible and perceptible. There is room therefore for a lifting effect that is, at the same time, easy to be managed, very fast to appear, with a clearly visible effectiveness and safe. This is why we deemed interesting to carry out the test with a new cosmetic serum (Instant Lifting®).

The product is a serum rich in vegetal substances deemed with lifting effect (*Acmella Oleracea*) potentially able to quickly smooth out wrinkles. It also contains actives and extracts of vegetal substances with antioxidant and anti free-radicals actions (vitamins A, C and E, *Ginko biloba*), specifically addressed to decrease the consequences of skin-ageing. Moreover, the presence in the formulation of *Cucumis sativus* brings softening and lenitive effects for the skin.

The aim of the present study was then to evaluate the anti-wrinkle immediate lifting effect of the formula. We carried out the test by measuring instrumentally and with photographic images the effects of the product after 5 minutes from the application, to determine if Instant Lifting® could show the characteristics of an effective and immediate lifting anti-wrinkle, in women and men.

MATERIALS AND METHODS

The aim of the study was to evaluate the immediate lifting effect of the new cosmetic serum after its application on the skin of the face and on the back of the hands. The effectiveness of the product should be objectively demonstrated by the significant decrease of cutaneous roughness values (Ra, Rz) and by the evident decrease of photoaging skin signs.

The study was carried out in compliance with the quality assurance system requirements, according to the principles of good laboratory practices (GLP), as well as the principles estabilished by the World Medical Association in the Declaration of Helsinki. Each volunteer, before the beginning of the test, has read and signed the informed consent prepared by the investigators. Twenty seven volunteers have been enrolled, 24 (21 f, 3 m) were treated with Instant Lifting and 3 women with another cosmetic serum, as comparison group. Volunteers' selection has been carried out according to the following inclusion and exclusion criteria.

INCLUSION CRITERIA

- Race: Caucasian
- Age: 8 (7+1) women 50-55 years old; 8 (7+1) women 56-60 years old; 8 (7+1) women 61-65 years old; 3 males 55, 60 and 65 years old
- Subjects with evident wrinkles on the face (especially in the periorbital area and in the lip contour) and signs of photoaging on the hands
- Absence of pathologies in the time immediately preceding the study or in progress
- Reliability

EXCLUSION CRITERIA

- Subjects in topical or systemic treatment with any drug possibly interfering with the results of the test
- Pregnant and breast feeding women
- Subjects with cutaneous diseases
- Subjects with known allergy or anamnestic intolerability to drugs and/or to cosmetics

DROP-OUT

The following reasons were considered as a cause of study interruption:

- free choice the subject
- reasons not correlated with the treatment (e.g.: arising diseases, surgical interventions, etc)
- reasons linked with treatment (e.g.: irritative, allergic reactions)

Details of any case of drop-out are anyway included.

SETS FOR INSTRUMENTAL EVALUATION

a) Image analysis, Monaderm

To obtain negative imprints of skin surface (skin replicas), the following materials was used:

- a fast hardening synthetic polymer (SILFLO-Flexico Ltd, United Kingdom)
- adhesive disks (3M, 24x40)

The adhesive disk is placed onto the subject's skin in order to delimitate the investigated area and to avoid possible skin stretching during the polymer application. A little amount of polymer is activated with a catalyst addition and is then spread within the circular area of the disk and left in situ for a few minutes until it becomes dry. The disk is then removed and a duplicate of the skin is faithfully impressed.

The skin replicas are then analyzed by a designed image processing software (Quantilines, Monaderm) which allows a global data analysis of some relief parameters, according to the method described by Corcuff.

Each silicon replica of the cutaneous surface is lightened by a light source with a defined incident angle (35°) with the purpose of generate shadows: the higher the furrows, the wider the shadows.

The main wrinkles must be oriented perpendicularly to the incident light. An image covering a 12 x 9 mm of each skin replica surface is acquired through a video-camera (High Performance CCD camera, COHU).

The software allows the measurements of the following parameters:

- Ra = mean roughness value
- Rz = maximum roughness value (deep wrinkles)

The anti-wrinkles effectiveness can be proved by a decrease of Ra and/or Rz values at the end of the treatment.

b) Fotofinder Dermoscope Ver. 2.0

The Fotofinder Dermoscope is a powerful and versatile system that allows to carry out and memorize the recorded images of any skin surface. The system is composed by an high definition colour videocamera able to magnify by means of a series of magnifying lenses every surface on which it is placed.

The digital images are visualized on the screen with their real colors. This allows to the observer to discriminate even the smallest details.

METHODS

a) Execution

Basal and final instrumental measurements have been carried out in a bioclimatic room (24+/- 2°C; 50 ±10% rh). The day of the test the volunteers have been asked not to apply any cosmetic or make up product on the face and on hands. The test has been carried out with the application of the product Instant Lifting® in 21 females (divided into age-groups) and 3 males (55,60 and 65 years old, average: 58,3) according to the following procedure. Before the product application to the female volunteers the cutaneous replicas were taken of perior-

bital, of lip contour and back of the hands areas. To the 3 male subjects the replicas were taken for periorbital and back of the hands areas only. Furthermore digital images of the same areas were taken for all subjects. After the basal evaluations, the technician applied a fixed amount of serum according to the instructions suggested by the manufacturer:

- apply maximum 2 or 3 drops of the product on the whole face (from hairline to neck) and 1 drop on the back of the hand
- spread it on eyelids, under the eyes, around the lips and on all the areas with wrinkles
- apply gently without rubbing the skin
- let the skin dry for 2 or 3 minutes

Skin replicas and digital images were taken again 5 minutes after the product application.

b) Mathematical elaboration

On the base of the results of normality test (Kolmogorov-Smirnov test, Lillefors test and Shapiro- Wilk test) the data could be considered parametric. The mean values and standard deviations were calculated for the Ra and Rz values recorded before and 5 minutes after the product application. Furthermore the variation of the values and the percentage of variation were calculated. The initial and the final values and the resulted variations were compared by means of dependent samples t-test. The differences between the groups of values were considered significant when the probability p is < 0.05.

RESULTS

IMAGE ANALYSIS

Product: Instant Lifting®

(n.: 21 women)

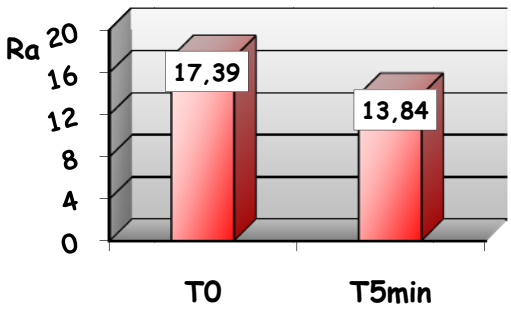
PERIORBITAL AREAS

A significant decrease ($p<0.0001$) of mean roughness values (Ra) was detected for the periorbital area, 5 minutes after product application (Table 1, Figure 1).

Table 1 Periorbital areas (Ra = mean roughness values; data are reported as mean ± standard deviation)

	T_0	T_{5min}	Δ	Δ%	t–test T_0 *vs.* T_{5min}
INSTANT LIFTING®	17,39 ± 2,29	13,84 ± 2,42	- 3,55	- 20,4	p < 0,0001

Figure 1 Periorbital area (Ra = mean roughness values)

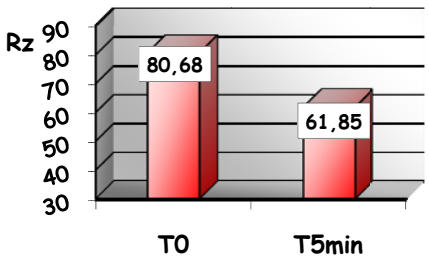


With Instant Lifting® a significant decrease ($p<0.0001$) of maximum roughness values (Rz) was detected for the periorbital area, 5 minutes after product application (Table 2, Figure 2).

Table 2 Periorbital area (Rz = maximum roughness values; data are reported as mean ± standard deviation)

	T_0	T_{5min}	Δ	Δ%	t–test T_0 *vs.* T_{5min}
INSTANT LIFTING®	80,68 ± 7,39	61,85 ± 15,10	- 18,83	- 23,3%	p < 0,0001

Figure 2 Periorbital area (Rz = maximum roughness values)



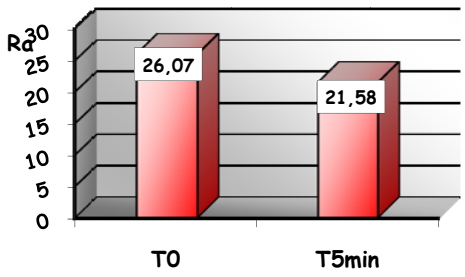
LIP CONTOUR

With Instant Lifting® a significant decrease ($p<0.0001$) of mean roughness values (Ra) was detected in the lip contour area, 5 minutes after product application (Table 3, Figure 3).

Table 3 Lip contour (Ra = mean roughness values; data are reported as mean ± standard deviation)

	T_0	T_{5min}	Δ	Δ%	t–test T_0 *vs.* T_{5min}
INSTANT LIFTING®	26,07 ± 3,32	21,58 ± 3,36	- 4,49	- 17,2%	p < 0,0001

Figure 3 Lip contour (Ra = mean roughness values)

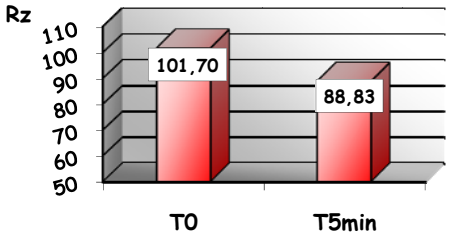


With Instant Lifting® a significant decrease ($p<0.0001$) of maximum roughness values (Rz) was detected in the lip contour area, 5 minutes after product application (Table 4, Figure 4).

Table 4 Lip contour (Rz = maximum roughness values; data are reported as mean ± standard deviation)

	T_0	T_{5min}	Δ	Δ%	t–test T_0 *vs.* T_{5min}
INSTANT LIFTING®	101,70 ± 9,16	88,83 ± 7,81	- 12,87	- 12,6%	p < 0,0001

Figure 4 Lip contour (Rz = maximum roughness values)



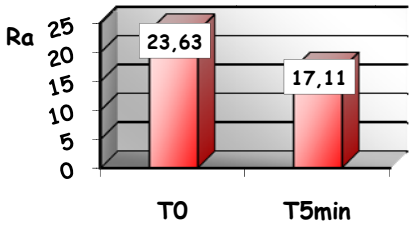
BACK OF THE HANDS

A significant decrease ($p<0.0001$) of mean roughness values (Ra) was detected for the back of the hands areas, 5 minutes after product application (Table 5, Figure 5).

Table 5 Back of the hands areas (Ra = mean roughness values; data are reported as mean ± standard deviation)

	T_0	T_{5min}	Δ	Δ%	t–test T_0 *vs.* T_{5min}
INSTANT LIFTING®	23,63 ± 3,97	17,11 ± 5,34	- 6,52	- 27,6%	p < 0,0001

Figure 5 Back of the hands area (Ra = mean roughness values)



With Instant Lifting® a significant decrease ($p<0.0001$) of maximum roughness values (Rz) was detected for the back of the hands areas, 5 minutes after product application (Table 6, Figure 6).

Table 6 Back of the hands areas (Rz = maximum roughness values; data are reported as mean ± standard deviation)

	T_0	T_{5min}	Δ	Δ%	t–test T_0 *vs.* T_{5min}
INSTANT LIFTING	107,20 ± 15,54	77,89 ± 25,30	- 29,31	- 27,3%	p < 0,0001

Figure 6 Back of the hands area (Rz = maximum roughness values)

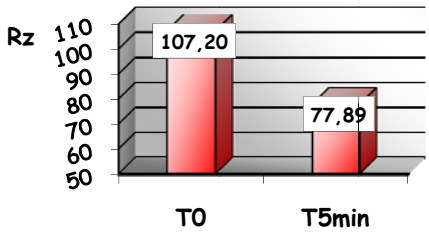


Image analysis

Product: Instant Lifting®

(n.: 3 men)

In the following tables the results observed in male subjects are reported.

Table 7 Periorbital areas (Ra = mean roughness values)

	T_0	T_{5min}	Δ	Δ%
INSTANT LIFTING®	19,44 ± 1,60	18,00 ± 3,69	- 1,44	- 7,4%

Table 8 Periorbital areas (Rz = maximum roughness values)

	T_0	T_{5min}	Δ	Δ%
INSTANT LIFTING®	86,84 ± 10,55	79,54 ± 14,08	- 7,30	- 8,4%

Table 9 Back of the hands areas (Ra = mean roughness values)

	T_0	T_{5min}	Δ	Δ%
INSTANT LIFTING®	27,80 ± 2,00	21,21 ± 5,44	- 6,59	- 23,7%

Table 10 Back of the hands areas (Rz = maximum roughness values)

	T_0	T_{5min}	Δ	Δ%
INSTANT LIFTING®	mean 123,03 SD. 5,24	mean 94,80 SD. 19,21	- 28,23	- 22,9%

Together with the image analysis also photographic images before and after 5 minutes from Instant Lifting® application was taken.

Periorbital area

T0

t5min

Lip contour

T0

t5min

Hands

T0

t5min

CONCLUSIONS

The aim of our test was to evaluate if the product Instant Lifting® could induce an immediate lifting effect after its application on the wrinkles of face (periorbital, lip contour) and of back of the hands.

Our experiments show that 5 minutes after the application in 21 women, the roughness decrease in of the tested areas always resulted significant ($p < 0.0001$) in comparison with basal values, either for mean roughness values (Ra) or for maximum roughness values (Rz). In detail, we found for periorbital area -20.4 % (Ra) and – 23.3% (Rz). For lip contour we found -17.2% (Ra) and -12.6% (Rz).

For the back of the hands area the results were -27.6% (Ra) and -27.3 (Rz). In the group made by 3 male subjects the effect on the lip contour was not tested. But also in this case, we detected very interesting results particularly on the back of the hands: -23.7% (Ra), – 22.9% (Rz).

An indicative pilot test carried out versus a market leader cosmetic serum, showed the superiority of product Instant Lifting®. The related data are not mentioned here because they are preliminary only. All the subjects participating to this test expressed satisfaction for the immediate results with the tested formula. Spontaneous requests concerned additional samples to continue the personal use. According to the described evaluation, the new cosmetic serum Instant Lifting® fits very well with the requirements of an immediate lifting effect (5 minutes), which can provide to both men and women the required self- confidence and self-esteem in special social occasions (like theatre or a date) or for better appearance in everyday's modern life.

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