

Case report

Eva Endosphères Therapy: a non invasive treatment for face aging

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Compressive microvibration consists of a series of rapid vibratory movements transmitted to the tissues with a succession of "pressure and vibrations". The mechanical oscillations of defined amplitude and frequency in relation to the resistance of the tissue, act on the cutaneous and hypodermic structures, but also on the muscular and tendinous apparatus, thus interconnecting with the deep muscular band. The compressive microvibrations are obtained by means of a special "honeycomb" arrangement of the 55 soft silicone spheres which, placed in a cylinder containing a sophisticated system of misarranged axles, rotate around themselves with rapidity, causing a pulsed and rhythmic movement. It is precisely in the variation of the frequency, pressure and vibration, that the secret of the various therapeutic responses is obtainable, with analgesic action, draining, vascularizing, trophic and restructuring, finalized with the reduction of connective and deep muscular pain, using the physiological regenerative reactions. From experiences using Endosphères Body, we have observed the results using the new methodology Endosphères Face EVA in nine volunteer ambulatory patients requiring this not invasive treatment to increase skin lightness and reduce face wrinkles. Using Antera 3D Camera for Skin Surface Analysis before and after six sessions of treatments in 13 weeks, we have valued the improvement of cutaneous roughness (20,5%) skin brightness (7,79%) and increase in vascularization by hemoglobin diffusion (28,5%), thus the satisfaction of patients valued 8,11 (from 1 to 10). All treatments presented no side effects or complications.

Called *Endosphères Therapy*, in 2006 the first "Compressive Microvibration" methodology was created, a new Italian bioengineering device that allows a new physical therapy for non-invasive treatments, exploiting the characteristics of particular receptors of our tissues (1, 2).

The new operative methodology reversed the principle of massage with aspiration and traction

that was used by most of the methods in the past, both for the treatment of oedematous cellulitis and for the treatment of fibrosis and skin laxity, proposing a technique able to stimulate, modifying the resistance and elasticity of the connective tissue, to restore the correct functional fluidity and favouring, in the meantime, a muscular relaxation by mechanical oscillations at studied frequencies.

Dermal receptors

Inside the tissues exist typical corpuscles that are sensitive to various stimuli (mechanical, thermal and painful), they are called

mechanoreceptors, harmful receptors and thermoreceptors.

When stimulated or compressed, or subjected to traction or vibration, they emit signals that favour various activities, including:

- A physiological lymphatic drainage;
- An activation of endorphins reducing pain;

- Stimulation of the muscular bands that activate the vascularization;
- Activation of the microcirculation regulating the physiological temperature;
- Activation of collagen modulation;
- The toning and trophism of tissues.

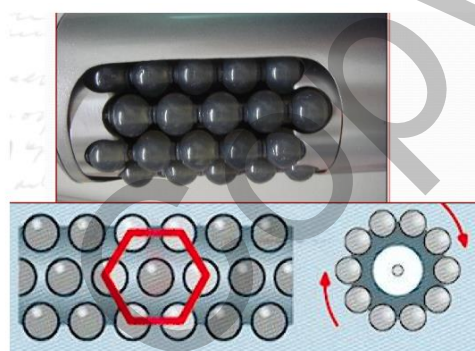
The compressive microvibration

The new methodology consisted of a series of rapid vibratory movements transmitted to the tissues with a succession of "pressures and vibrations" made in such a way that the contact between microspheres and tissues was never interrupted.

The mechanical oscillations, of defined amplitude and frequency (studied on the resistance of the tissue), act on the cutaneous and hypodermic structures, but also on the muscular

and tendinous apparatus, both relaxed and in tension, thus interconnecting with the deep muscular band.

The typical microcompressive vibrations are obtained by means of the special "honeycomb" arrangement of the 55 soft silicone spheres which, placed in a cylinder containing a sophisticated system of misarranged axles, quickly rotate around themselves, causing a pulsed and rhythmic movement (Fig. 1-2).



Synergistic Actions

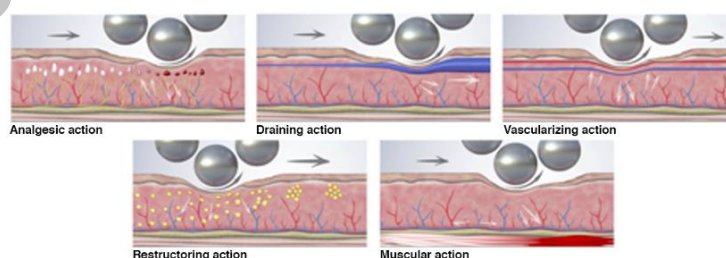


Fig. 1-2. *Honeycomb position of rotating microspheres in the handpiece, at the right different actions achievable with different pressure and rotation frequencies of the microspheres.*

It is precisely in the variation of the frequency, pressure and vibration, the secret of the various therapeutic responses obtainable, with analgesic

action, draining, vascularizing, restructuring and trophic, with a final reduction of deep connective and muscular pain (3, 4).

Action mechanism

Endosphères Therapy allows to work on both the connective tissue and on the main muscular groups, causing a remarkable sedative action on the hyperexcitability of the motor and sensory nerves, thus reducing the contracture and the pain. In addition, a significant hyperemia is generated for increased vascularization, which improves the uptake of oxygen and promotes the correct muscular and tissue trophism.

The action on the lymphatic system is favoured by the different spatial position of the spheres that favours the action on the dermis, with a pulsed and rhythmic action in the form of a "wave" that pushes the lymph, like a pump, towards the lymph nodes, thus producing an endodermal massage that reactivates the lymphatic system and the connective tissues.

The action mechanism of the method is based both on the "pressure and rotation" of the microspheres, and on the movement of the operator's hand that manages them, with a

mechanical microvibration on the tissues at a low frequency (from 29 to 384 Hz).

This action allows the modelling of adipocytes and skin structure, vasodilatation with immediate subsequent vasoconstriction in order to reactivate blood circulation in localized areas. It also stimulates the corpuscles tissue receptors to obtain a lymphatic drainage and connective tissue restructuring response with an increase in cutaneous, subcutaneous and muscular tonicity (5-7).

A long experience in sports medicine and in the construction of sports equipment, has led the Italian industry engineers to refine the system with compressive microvibration, whose operational characteristics were then confirmed by studies carried out mainly by the staff of Professor Saggini and prof.ssa Bellomo, from the Department of Physical and Rehabilitative Medicine at the University of Chieti, then by prof Bacci, at the Siena University.

The "Orange Peel"

One of the most effective actions of the Endosphères treatment takes place precisely on fibrosclerotic and fibroedematous alterations of the connective tissue, on those areas with "orange peel" so-called female cellulitis, particularly difficult to eliminate.

The localized and constant action of the roller and the microspheres rotating on the dermis, thanks to the compressive microvibrations transmitted to the tissues in

the muscular band, favours a functional metabolic activation with a reduction of lipodystrophic adipocytes that redistribute so as to reshape the skin contour, thanks a physiological apoptosis resulting in tissue regeneration and restructuring in the necessary time (three to six weeks), especially if associated with a good nutrition.

Compressive Microvibration may be the basic therapy which can be used in various

The technical evolution

Ten years of experience have made it possible to obtain an interesting technical evolution with a new generation of devices, named “*Sensor System*”, where the cylindrical handpiece that houses the silicone microspheres is totally controlled by a microcomputer that manages its functions.

New sensor of which the handpiece has been

edematous alterations, fibroedematous or pain of the tissues (8).

equipped, make it able to manage autonomously the pressure and the frequency according to the data that the patient's tissue transmits, thus adapting the treatment to the individual's needs. All this has made the treatment more precise, reducing the operator's errors and expanding the possibilities of the treatment itself (Fig. 3).



Fig. 3. *The new Sensor handpiece that automatically controls the microspheres.*

Based on the results obtained by the body treatment with Endospheres Therapy, in consideration of the characteristics of action related to the particular "honeycomb" arrangement of the microspheres placed in the cylinder, we know that the various pressures stimulate the different connective receptors that activate vascular, metabolic, painkilling and restructuring actions.

The elastic response of tissues, favoured by microspheres, creates microuphavals and tissue translations that generate a "vascular gymnastic"

to justify the significant oxygenative and thermal improvement highlighted in the treated zones.

On these technical bases and on the various experiences, researchers realized a new device for the non-invasive face treatment, characterized by a handpiece suitable for the contour of the face and neck, with the following parameters:

- *Rotating microspheres handpiece with 60 soft silicone microspheres*
- *Microspheres rotating between 60 and 350 Hz of frequency*

— *Microspheres located in different position of the axes*

The new device consists in the combination of three handpieces, which are matched in the complete protocol treatment, creating a series of detailed actions. The new handpiece, called “M.A.S.”, is able to create a combined action of sensorized microablative compressive microvibrations, because the handpiece is equipped with a system of spheres positioned on a rotary axis and staggered at 13.7° which creates a friction on the skin.

The traction caused on the tissue by the combined action of position and movement of the microspheres, causes a soft removal of the superficial epidermal layer, for a superficial soft “gommage” that increases oxygenation and

regeneration of the tissue.

Simultaneously, a tissue stretching effect is created, particularly on the wrinkle line, thus obtaining a combination of interesting results. In association to the “MAS” handpiece, new device has also a new “FACE” handpiece, also equipped with a series of gel microspheres with a density of “15 shore” which are able to arrive at the muscular level, at the vascular level, for a vascularizing and draining action.

The operator uses either handpiece according to the different indications, while the first handpiece has a smoothing action on the epidermis, the second has the typical vascularizing and restructuring action of the compressive microvibration (Fig. 4).

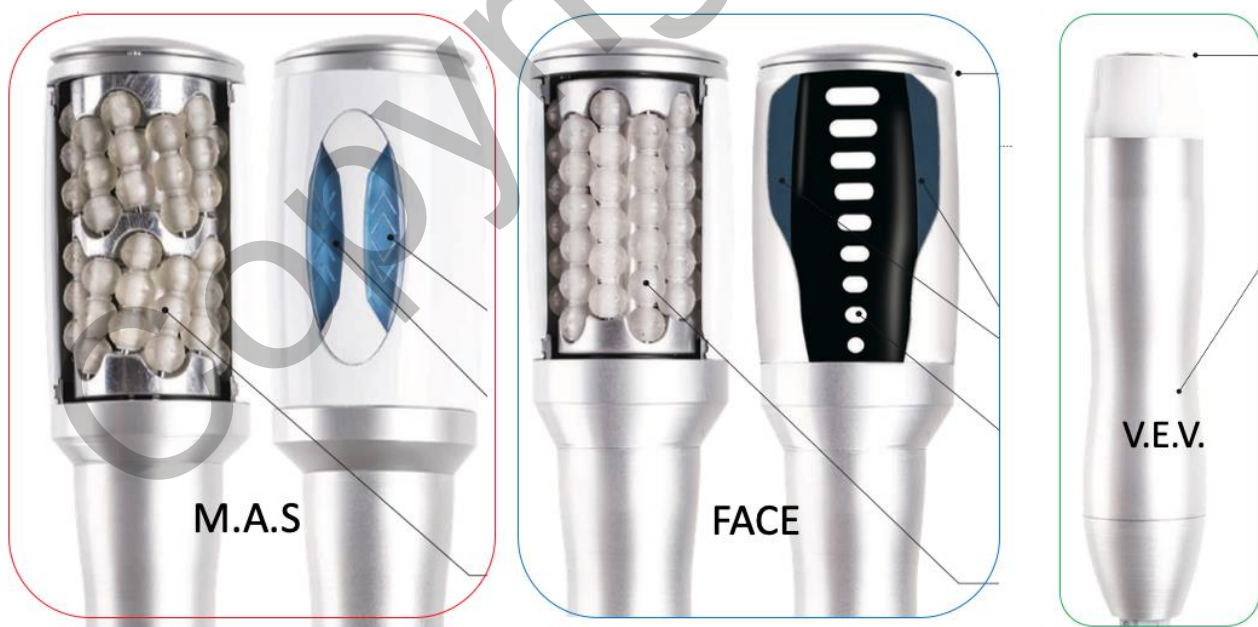


Fig. 4. MAS: the ultrasoft microspheres positioned in different rotary axis, FACE: the soft microspheres in harmonic rotary axis, VEV: the vibro-electro carrier.

The equipment also has another handpiece, called "V.E.V.", which is a vibro-electro carrier by square waves that allows to convey active substances possibly necessary for therapy.

The present study was done utilizing a precise protocol with two sessions per week for five weeks.

Based on the concept that the good results should have come thanks to the increase of the skin temperature and good vascularization, to the

improvement of the hydration and oxygenation of the tissues, to the lymphatic depurative drainage and new mitochondrial respiratory activity, the purpose of the study was:

- *Cutaneous thermal increase with visual reduction of aging signs*
- *Tissue Toning with patient satisfaction*
- *No side-effects and good tolerance*

Materials and methods

Using a new device, a clinical, non-invasive and non-experimental observational study was promoted to evaluate the characteristics of the treatment and for a better understanding of the effects of the new non-invasive "EVA Endosphères Therapy".

- Nine volunteer patients were selected between the ages of 22 and 62 years (1 male and 8 females) who had spontaneously asked to undergo this non-invasive treatment for the rejuvenation of the face, the goal of the study was to detect aesthetic changes after face treatment using the new "EVA Endosphères Therapy".

- All nine patients were treated according to the standard protocol by training physiotherapists, supervised by Prof Pier Antonio Bacci, between October 1st, 2018 and January 30th, 2019.

The study developed in 5 sessions and carried out as follows:

- *the second session, 7 days after the first session*
- *the third, 15 days after the second*
- *the fourth, 21 days after the third*
- *the fifth, 28 days after the fourth*
- *final check three weeks after the fifth*
- The study had to include only voluntary patients who had expressly requested to undergo this treatment.

Patients who undertook hypotensive therapy, cortison, chemotherapy, diuretic treatments, and those treated with fillers or lasers were excluded from the study, while patients with facial signs of aging that may be treated by cosmetic physiotherapy methods, lasers, dermocosmetics or cosmetic medicine, had been included in the study.

- Patients had been expressly asked not to change their eating habits and lifestyle and not to use chemical peels and cosmetic medicine treatments during the study period.

Treatment protocol

- a) Five sessions were performed as per standard protocol
- b) First treatment was on October 1st, 2018.
- c) The Antera 3D Camera images were done before the first treatment and at the end of the treatment after 13 weeks.
- d) The Antera images were taken in the right nasolabial folds, in the procerus and in the right periocular area.
- e) By the Antera photographic test we can evaluate the average reduction of cutaneous roughness, the average reduction of cutaneous melanin, the average increase in vascularization for hemoglobin diffusion and the improvement of cutaneous trophism. Finally, percentage ratios of possible improvements are made, with observations and conclusions.
- f) A questionnaire was added for physician and

patient satisfaction using VAS Scale, as well as the detection of side effects and complications. In the satisfaction questionnaire, the patient had to give a judgement from 1 to 10, where 5 is the line of demarcation between satisfactory and unsatisfactory on the following:

- *Has the roughness decreased?*
- *Are the wrinkles fuller and less visible?*
- *Are the wrinkles a rosier colour?*
- *Are you satisfied with the results?*

All patients included in this study were volunteers and had expressly requested to undergo Endosphères Eva face treatment in the standard protocol. All data are protected by privacy (DLG. N. 196 of 30/06/2003) and the informed consensus, with authorization of the face photos, preserved in the FenixGroup archive.

Antera 3D Camera

In the diagnostic study, the non-invasive "Antera 3D Camera Miravex" for skin surface analysis was used. This digital camera captures photos that the computer processes with the possibility of also seeing the photo also in three-dimensional versions and in various spatial positions. The Antera 3D Camera combines real 3D imaging with high measurement precision, standardized lighting conditions, versatility of measurements and powerful data analysis (9-11).

This methodology is easy to use, image acquisition is fast, as is export and analysis of data. The field of view of the camera is 56x56mm (2.2" c 2.2"), it has a scientific significance and allows to perform comparative reports in relation to skin variations regarding "*Structural differences, Variations in tissue hemoglobin content, Differences in the content of tissue melanin and Variation in tissue roughness*".

Results

Data detected by the *Antera 3D Camera* is evaluated in the photos performed at the first treatment and after three weeks from the last treatment (the fifth session), noting the percentage of the, melanin and hemoglobin variation, as well as the overall structure of the treated area of the

face in the right side.

Roughness – The results show an average reduction in the roughness of the treated area of 20.5% (in particular 16.08% in the periocular area, 17.03% in the forehead and 27.35% in the right nasolabial fold) (Fig. 5).

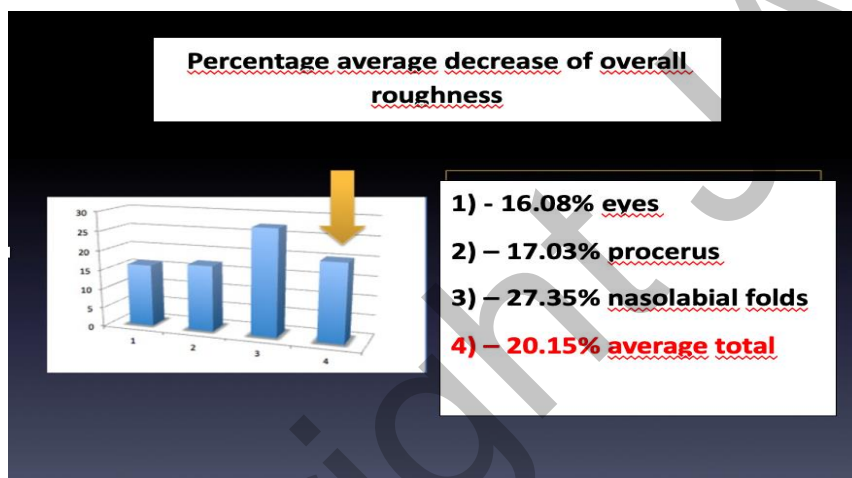


Fig. 5. Average roughness Improvement.

Melanin – The results show an average melanin reduction of 7.79% (In particular 7.12% in the

periocular area, 6.96% in the forehead and 9.31% in the right nasolabial fold) (Fig. 6).

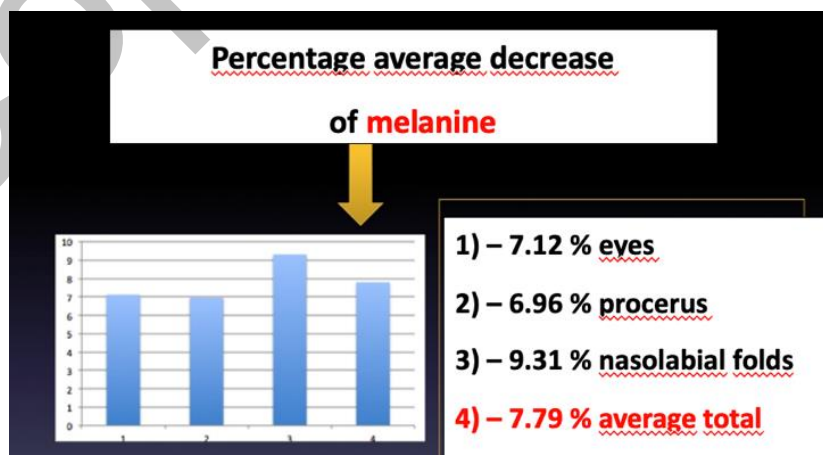


Fig. 6. Average melanine reduction.

Hemoglobin – The results show an average hemoglobin increase of 28.5% (In particular 26.28% in the periocular area, 26.2% in the

forehead and 33% in the right nasolabial fold) (Fig. 7).

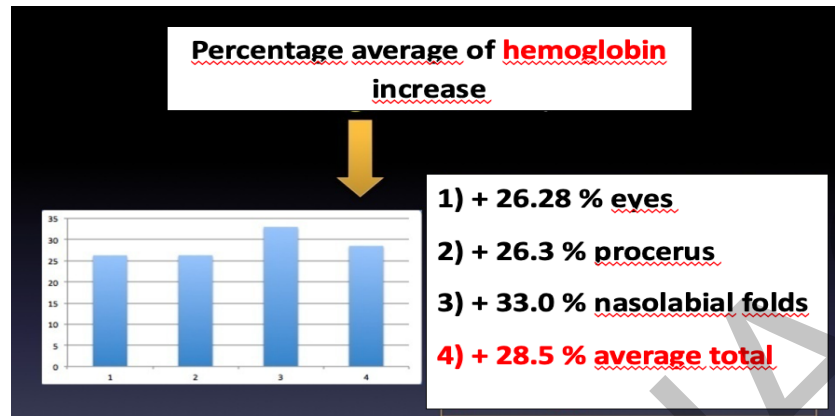


Fig. 7. Average hemoglobin tissue improvement.

Trophism Tissue – The results show a constant improvement of the trophism tissue of 9.05% (in particular 9.25% in the periocular area, 11.05% in

the forehead and 6.85% in the right nasolabial fold) (Fig. 8).

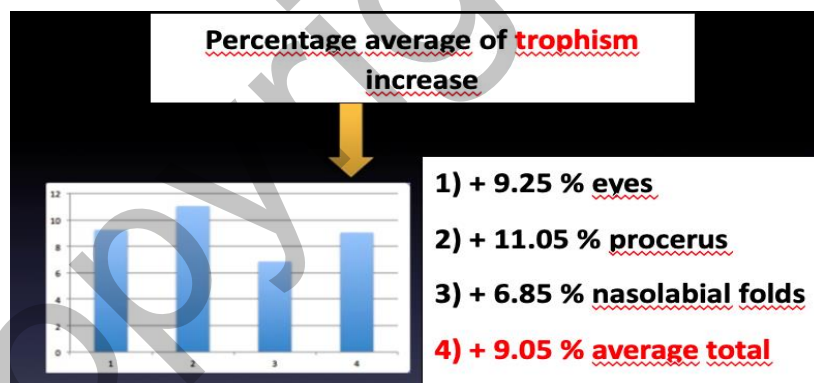


Fig. 8. Average woven trophism increase.

Patient satisfaction data

At the end of treatments, patients filled out an evaluation questionnaire to provide an assessment using a scale from 1 to 10, with 5 being the line of demarcation between sufficiency and insufficiency, between satisfactory and unsatisfactory, about the improvement of

roughness, skin color, rosiness aspect and trophism of tissues, in addition to the subjective satisfaction and to the tolerability and efficacy of the treatments.

Has the roughness decreased? Patient questionnaires revealed satisfaction in more than

90% of patients with a satisfaction rating of 7 of the visibility of face wrinkles (Fig. 9). (range between 3 and 9) in relation to the reduction

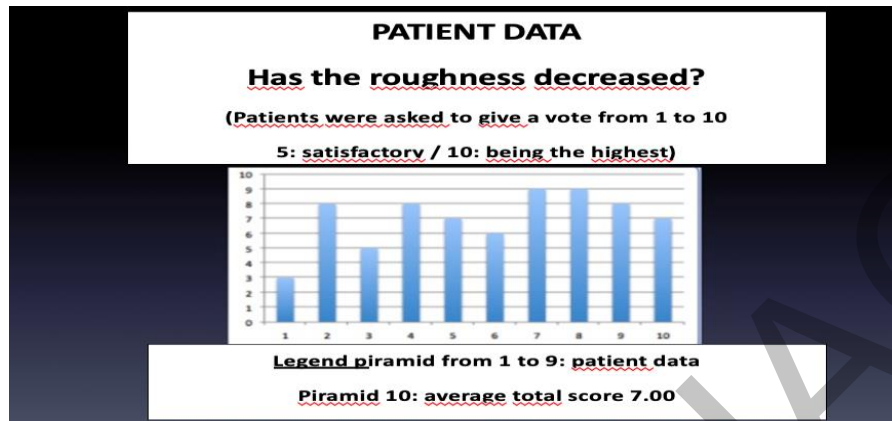


Fig. 9. Patient Satisfaction for Facial wrinkle reduction.

Are the wrinkles less visible and fuller? is detected in relation to the filling and
Satisfaction in more than 90% of patients with a compactness of face wrinkles, with lower visibility
satisfaction rating of 7.22 (range between 4 and 9) (Fig. 10).

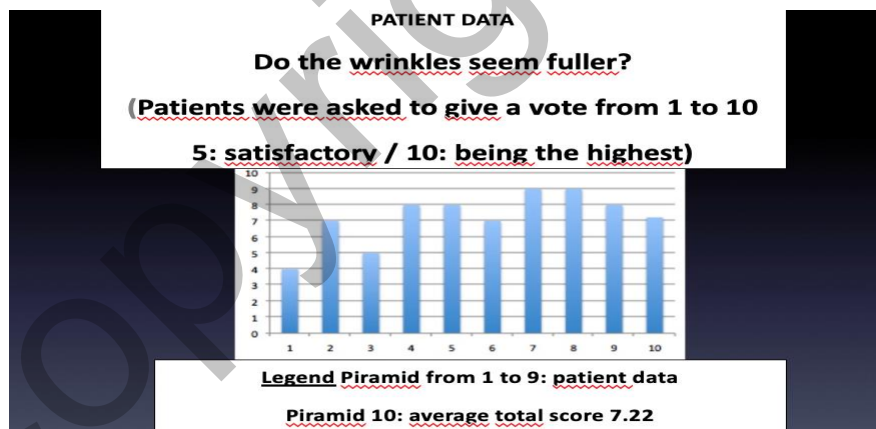


Fig. 10. Satisfaction for improved wrinkle consistency.

Are the wrinkles visibly pinker? Satisfaction in the better oxygenation of treated wrinkles, with
100% of patients with a 7.77 satisfaction rating lower visibility and rosy skin colouring (Fig. 11).
(range between 6 and 9) is detected in relation to

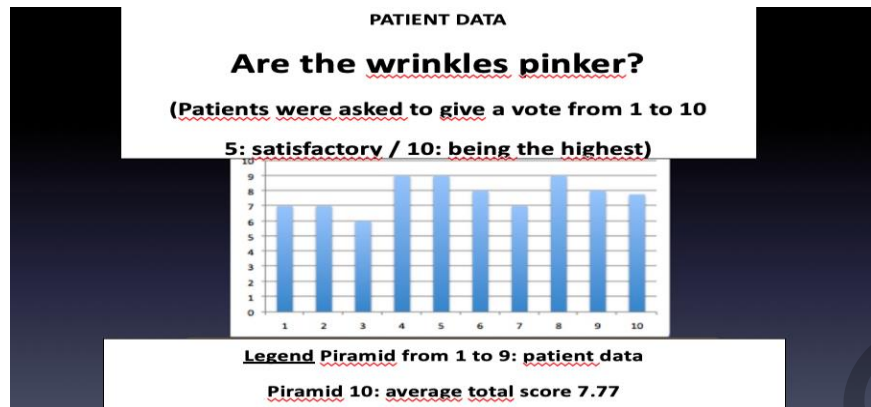


Fig.11. Satisfaction for skin oxygenation improvement.

Are you satisfied with the results? Satisfaction was found in 100% of patients with a 8.11

satisfaction rating (range 6 to 9) in relation to the result of the performed treatment (Fig. 12).

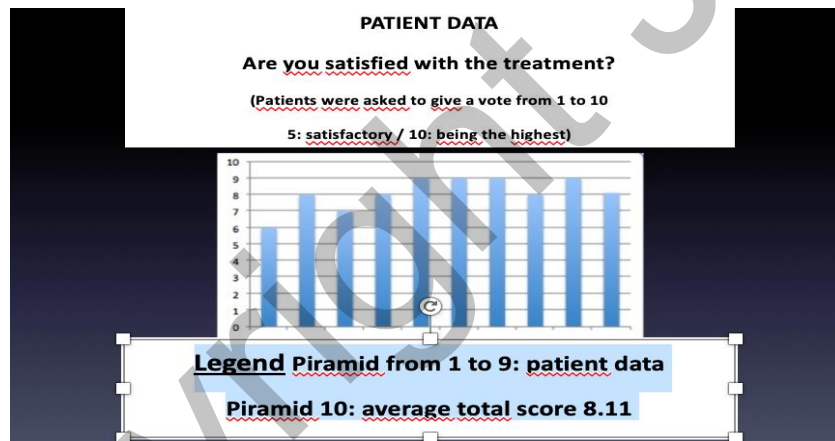


Fig. 12. Satisfaction with the treatment performed.

Tolerability – In relation to the tolerability, the patient expressed the judgement based on possible side effects and on his tolerability of the treatment,

with a judgement ranging from 3 to 10, as in the following scheme:

TOLERABILITY	POOR 3- 4 - 5	SATISFACTORY 6	Good tolerability 7 - 8	EXCELLENT 9 -10
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Good tolerability of treatment is declared by 100% of patients with a satisfaction rating of 8.66

of VAS Scale (range between 8 and 9) (Fig. 13).

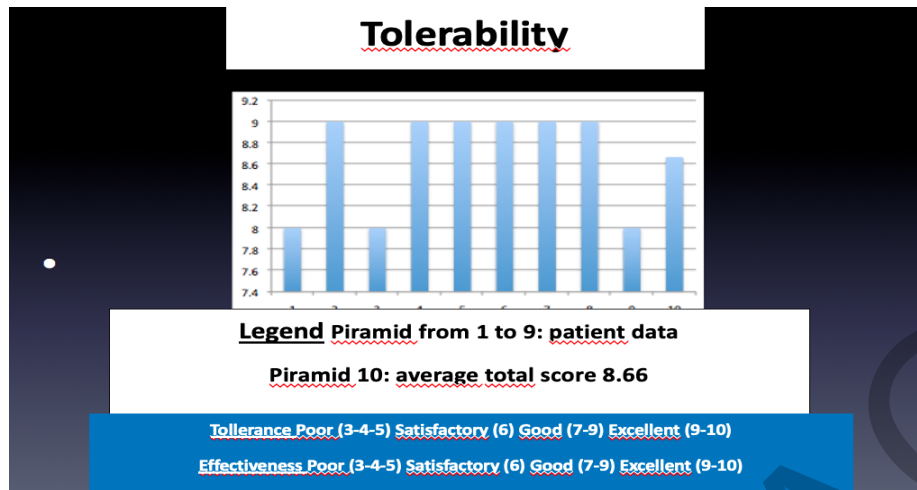


Fig. 13. Excellent treatment tolerance without side effects.

Effectiveness – In relation to the effectiveness, the patient expressed his judgement based on the

aesthetic result obtained and his degree of satisfaction, with a judgement ranging from 3 to 10, as follows:

EFFECTIVENESS	POOR 3 - 4 - 5	SATISFACTORY 6	GOOD 7 - 8	EXCELLENT 9 - 10
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Efficacy of treatment is declared by 100% of patients with satisfaction rating of 8.44 of VAS

Scale (range 7 to 9) (Fig. 14).

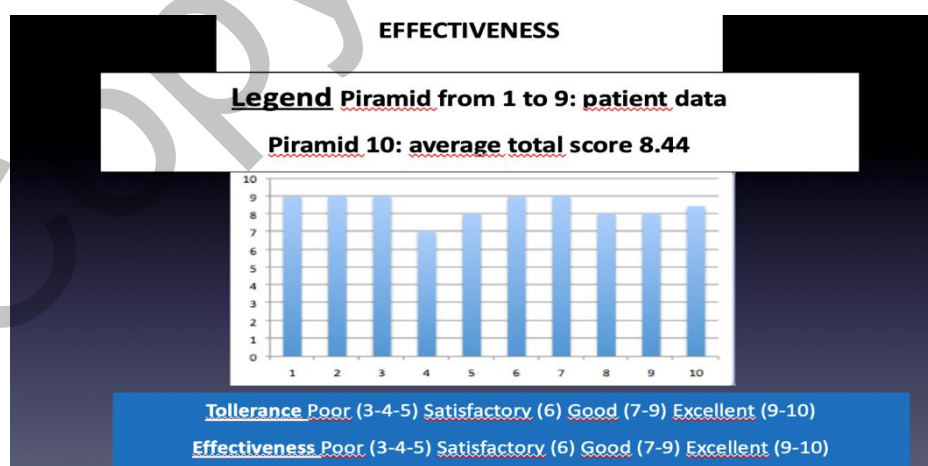


Fig. 14. Excellent treatment tolerance without side effects.

Discussion

The observation of the results reveals the positive activity of the methodology in smoothing and harmonise the skin irregularities and the cutaneous discheratosis, while favouring the tissue restructuring in their thicknesses. Dedicated considerations in the various fields can also be done.

Roughness – Using the “Face” handpiece we can obtain the stimulation of tissues, but using “MAS” handpiece we have a superficial microabrasion

useful for reducing the irregularities of the skin.

This handpiece is typically dedicated to epidermal regularization, as a soft and sophisticated “gommage” (microscrub).

A careful observation allows us to notice how to the smoothness improvement of the tissue always follows an increase in the compactness of the treated area, expression of the physiological processes of tissue regeneration (Fig. 15).

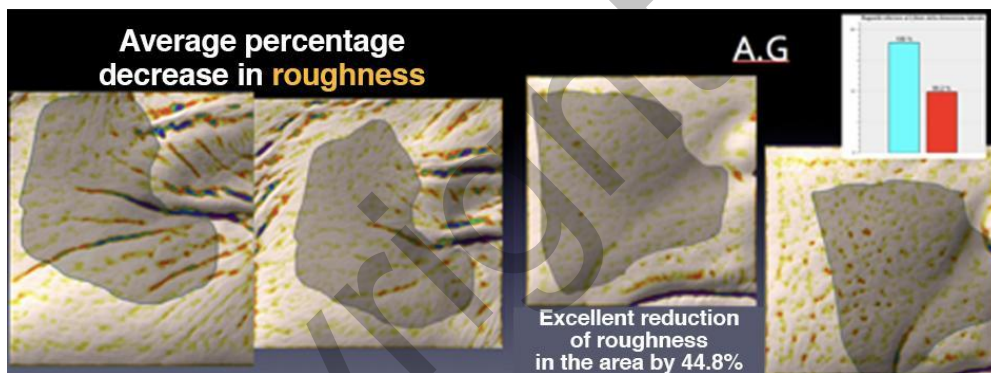


Fig. 15. The slides demonstrate the reduction of skin wrinkles.

The typical effects of the wrinkles reduction are associated with the visible effect of skin distension

and tissue restructuring that appears more compact and tonic (Fig. 16).

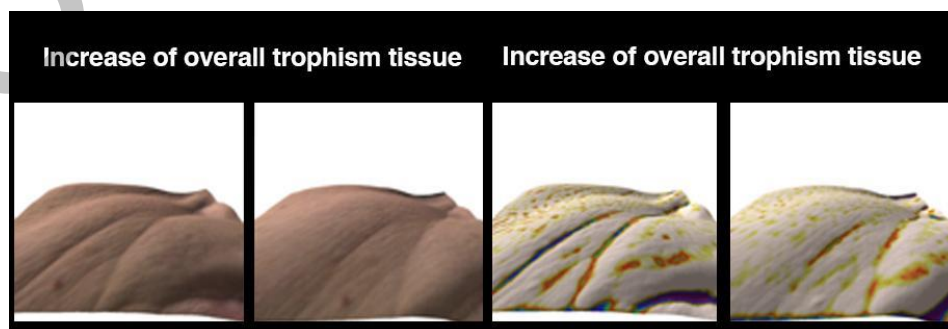


Fig. 16. Slides demonstrate the sharp reduction in skin roughness, increased tissue relaxation and compactness.

These effects found in the Antera 3D Camera photographs agree with the visual results perceptible in the patients, both objectively and subjectively, where a greater smoothness and skin gloss appears, with a sense of compactness of the

structure, an expression of improved oxygenative and metabolic activity.

The results are better highlighted at the end of the treatments, also for a better adaptation of the skin to the cosmetic correction by make-up (Fig. 17).



Fig 17. After 48 hours from the fourth treatment you have an idea of the optimal end result, with restructuring of the dermoepidermal and deep planes, for reactivation of the various metabolic activities.

Melanin – With the typical increase in skin luminosity and the reduction of dyskeratotic roughness, the effects of the treatments always show a reduction in skin pigmentation with a tendency to a "slight whitening" of the skin colour and a skin change from "greyish to rosy".

This is the normal effect of an epidermal microscrub favored by treatment using microspheres in ultra-soft silicone, with loss of old corneal cells and a replacement of a new more oxygenated tissue.

Reduction of the melanin highlighted by the Antera Camera is allowed both by the mechanical effect of the treatment, and above all by the metabolic and oxygen reactivation, whose regenerative effects can be highlighted along with the reduction of the degenerative processes of the matrix.

The rosy color is not so much due to the increase in vascularization and the amount of blood, but to the restoration of metabolic activities in the connective interstitial matrix (Fig. 18-19).

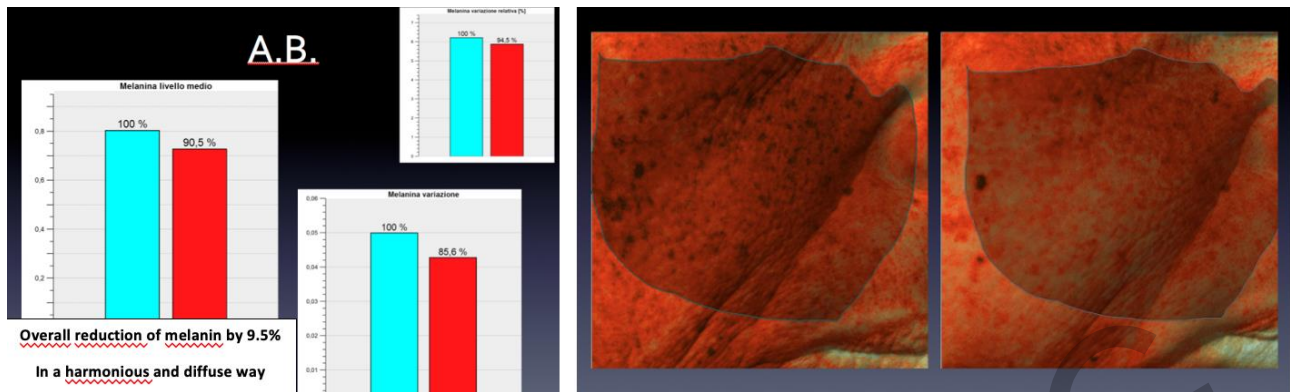


Fig. 18. The photos indicate the reduction of melanin in the treated area, in a harmonious and widespread way.

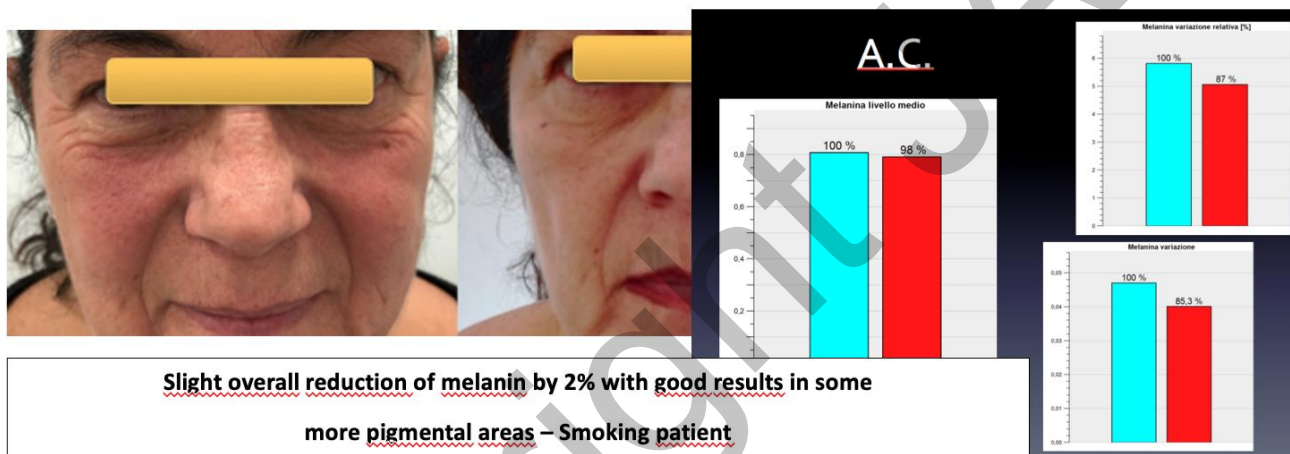


Fig. 19. This case indicates a small but significant reduction of melanin diffusely, but also indicates the presence of tissue oxidative stress.

Interesting are the results obtained in patients who smoke or have signs of aging characterized by oxidative stress and tissue hypoxia, all this indicates how important it is to always associate nutritional purification and hepato-intestinal rest, to reduce inflammation and histamine stimulations that alter the immunological responses and activate the processes of skin aging.

Hemoglobin – The effects of increasing the amount of tissue hemoglobin detected by the Antera photos are interesting in demonstrating the ability of the treatment to offer some useful

variables for the best aesthetic and clinical result.

The first being assessable with the greater smoothness and compactness of the skin, the second with the brightness and recovery of the rosy color of healthy skin.

Every mechanical or energetic stimulation on the skin produces an increase in the number of microvessels and, consequently, in the amount of blood that irrigates the tissues.

Almost always, this is reflected in the increase in the amount of hemoglobin detected, but sometimes this may not occur, especially in those who smoke,

who use hormones or drugs, who have cardiovascular diseases or a reduction in serum iron and transferrin, often associated with tissue acidity and metabolic alterations of the matrix.

The face treatment using EVA Endosphères Therapy increases the microcirculation and skin vascularization, the images demonstrate the variation of tissue hemoglobin (Hb) (Fig. 20).

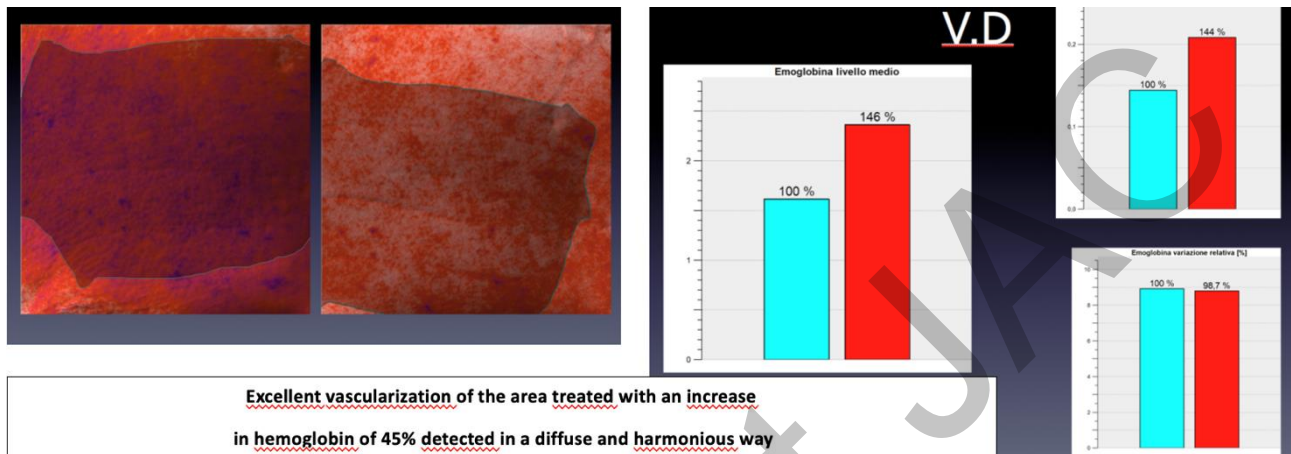


Fig. 20. A case with an important increase in vascularization and tissue hemoglobin.

However, we must interpret some variations that individuals with metabolic and oxygenative alterations may have.

Our study allows us to evaluate the "average Hb level", the "Hb variation" and the "relative percentage change in Hb".

- The graph "Medium-level hemoglobin" indicates the percentage or quantity of hemoglobin present in the area under examination: in good results, after the treatment this graph should always indicate a tendency to increase values.
- The "Hemoglobin Variation" graph indicates the uniformity of hemoglobin diffusion present in the area examined after the treatment.

Therefore, the higher the numeric data, the greater

the uniformity of the tissue diffusion in Hemoglobin Hb.

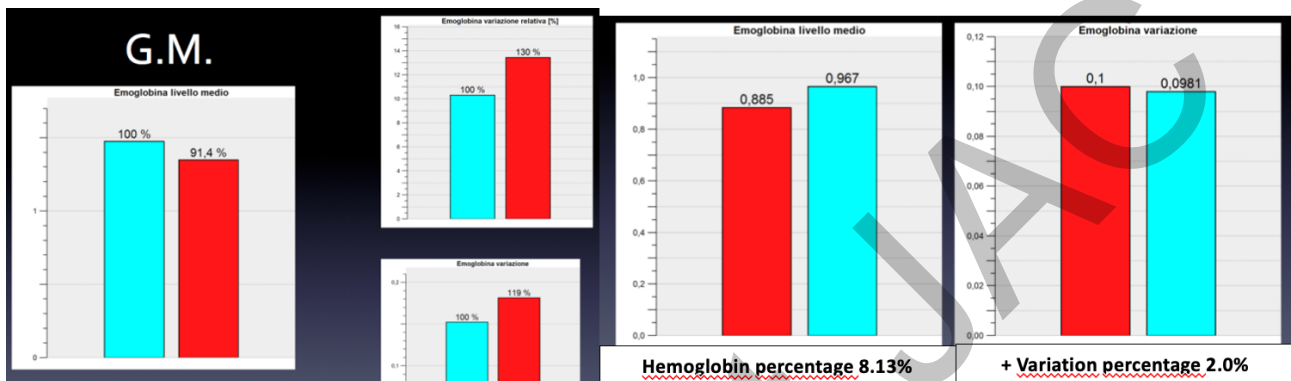
Therefore, in good results, after the treatment the graph should indicate an increase in values, in tune with the picture "medium level hemoglobin".

When an inversion exists in this way, it means that the treatment may have moved the ematic flows or a greater number of microveins did not rise at the same speed as the hemoglobins tissue, therefore of oxygenation.

This is typical phenomena of the fibrous cellulite and fibroedema, because of the presence of less vascularized areas (cellutitic nodules emersed in vascularized tissues) or in the areas with greater microarterial spasm (for example, the different face areas where signs of ageing vary due to the different dermoepidermal and subcutaneous

structure layer).

- The graph "*Hemoglobin Variation relative to percentage*" indicates the percentage of variation in the spread of hemoglobin present in the area under examination.



In good results, after treatment the graph should

Fig. 21. Two cases with data inversions that denotes areas of arteriolar spasm and needs to associate purifying methods and ossigenative.

Endosphères Eva 2019 has shown that:

- a) the new device allows a non-invasive and highly effective treatment, which is pleasant, easy to use and free of side effects.

- b) The new device allows non-invasive treatments with predictable and constant results, useful both in the corrective and prevention and maintenance phases (12).

Conclusion

The results of the study demonstrated the improvement of the signs of the face skin aging with reduction of wrinkles, increase in the brightness of the skin, increase in temperature and vascularity, improvement in trophism and skin tone.

The results that can be obtained in face rejuvenation are:

- reduction of ageing signs with reduction of

wrinkles and skin roughness

- action of dermo-epidermal scrubbing without heat production
- action of epidermal microscrub without stimulation of Langerhans cells
- reduction of dyskeratosis and increase in epidermal smoothness
- increased skin brightness and reduced pigmentation

- *increased pinkish color of the skin with activation of oxygenation activities*
- *increased microcirculation and mitochondrial activity*
- *increased skin temperature*
- *drainage and oxygenation of the interstitial matrix*
- *stimulation of the plastic and regenerative activities of the matrix*
- *increased trophism and tissue water*

- *musculofascial stimulation with increased muscle tone*

This study about non-invasive antiaging treatment using “EVA Endosphères Therapy” has shown the full correlation between the indications and the aesthetic results obtained, proving this methodology useful for the prevention of the ageing processes and correction of initial signs of skin ageing.

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