CLINICAL

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FACE REVITALIZATION - BIOLIFTING WITH MD-TISSUE

SUMMARY

In our society there is a major interest in the treatment of ageing skin with revitalizers that stimulate new collagen production and that can enhance face luminosity and freshness without damaging the health of the patients treated.
The aim of this study is to demonstrate the efficacy of the medical device MD-Tissue as a face revitalizer. Fifteen female volunteers have been treated with weekly injections for six consecutive weeks; the evaluation has concerned only the nasolabial folds.

– A photographic documentation with Visioface® Quick has been carried out and the volume of the wrinkle has been calculated; during the treatment period of the elasticity has also been measured. The Collagen Medical Device MD-Tissue has been perfectly tolerated by all volunteers.
It has proven an average capacity in the improvement of the skin elasticity and a good capacity in the reduction of the wrinkle volume.

KEY WORDS

SKIN AGING - FACE REVITALIZATION - COLLAGEN MEDICAL DEVICE MD-TISSUE, VISIOFACE® QUICK, ELASTICITY, WRINKLE VOLUME

SKIN AGING

The aging of the skin – especially the one of the face – is a growing concern for most people, regardless of their age.

Patients can be very young, looking for tips to prevent wrinkles, or they can be middle-aged, desiring to look younger or at least keep their appearance unchanged. On other occasions patients start treatments when they are elderly, and have finally decided to do something for themselves.

– Skin aging depends on several factors: biological senescence and genetic heritage (chrono-aging), photo-aging due to UV rays, and finally on lifestyle (diet, alcohol, smoking, pollution and oxidative stress).
The appearance of the aged skin varies depending on the prevalence of chrono- or of photo-aging (1, 2, 3): the senile skin is pale and dry, thin, floppy, hypo-elastic and finely wrinkled, whereas the photo-aged skin is rough, patched and crossed by deep wrinkles, the skin is anelastic and the horny layer is thickened; the smokers' skin is also sallow and dull.

WRINKLES AND THEIR PATHOPHYSIOLOGY

The causes that lead to the formation of the wrinkles are – in addition to chronological aging as a whole – the degradation of the elastic fibers and the alteration of the collagen ones (caused by the sun), muscle and joint movements, and the force of gravity.

The formation of wrinkles is affected by these factors to different extents and – consequently – also in the classification of the aging degree.
The classification of the signs of aging conducted by Kligman (1) can help to identify the various stages of the aging process: linear wrinkles, glyphic wrinkles, creases, lines of articulation, nasolabial folds (4).
Linear wrinkles result from linear contraction of the mimic muscles of the face, when they lose tone and elasticity. At first they are temporary folds and furrows, then they mark the face increasingly, following the muscle movement.

For instance, the "crow's feet", around the eyes; the "wrinkles of wonder", parallel to the front; the "thinker's wrinkles", vertical at the center of the eyebrows, the "smoker's wrinkles" that surround the mouth.
All gradually become more marked in relation to the photo-induced damage.
Glyphic wrinkles – which other authors define as skin texture – are lines that form square or rhomboid areas on the skin surface; with aging they become more evident, they are particularly noticeable on the cheeks of the elderly with photo-damaged skin.
Creases – better known as "the folds of

sleep" – develop late, caused by the head resting on the pillow while sleeping.
Their vertical course crosses the vertical mimetic muscle lines, especially on the forehead and cheeks.
The lines of articulation are those found in places where there is a hinge movement (ankles, elbows, wrists, etc.); existing since the birth, they become more marked and increase in other zones too (neck, trunk, etc.) with senility.
They are not very much considered from the point of view of cosmetology and dermatology, nevertheless.

Finally, the nasolabial folds, which have been taken into consideration in this article, and the folds of muscle-skin laxity that appear when the collagen and elastic texture is no longer able to counteract the force of gravity and present themselves as a falling of the skin due to the force of gravity.

The loosening skin is the outward visible result of the degradation of the connective tissue in which collagen, elastin, fibronectin and proteoglycans have lost their cohesion, their strength and ability to respond to elastic stimuli.
This phenomenon is connected to aging or to prolonged sun exposure, or even to weight loss following a state of obesity (4).
Revitalizers are very suitable for patients who want a natural treatment which does not change the facial expression.
The possibility of using a revitalizing such as **MD-Tissue** could offer many advantages. It is a product that has been planned for soft tissues, able to create a defense barrier against free radicals and to counteract the physiological aging of connective tissue (5).
These are all properties required for the use of a good tissue revitalizer.

Homeopathized collagen has been used since the 90s (Kollagen D6, D8) and after the first encouraging results, more revitalizing substances have been added.

Thus, the product **MADE** was born; it contains Collagen D8/D30, Hyaluronidase D8/D30 and Magnesium D6 (6).
Collagen D8/D30 works by stimulating the production of endogenous collagen, because – according to the law of the Arndt-Schultz reverse effect – weak stimuli (diluted doses) excite the biological activity.
The Hyaluronidase D8/D30, acting with the mechanism of the inverse effect, encourages greater compactness of the basic substance reducing wrinkles and toning the skin.
Magnesium D6 stimulates the production of exogenous collagen too.
– MADE also contains enzymatic catalysts, which act on the cellular respiration, drainers and organotherapy medicines with toning and revitalizing effects (6).

THE TUNNELING TECHNIQUE

Tunneling represents an infiltrative technique which consists in introducing the needle (in this study it was used the 27G needle) for its entire length almost tangentially to the skin surface, so to take wrinkles or nasolabial folds for their entire length.
Once introduced the needle, one starts to inject the substance and simultaneously pulls the syringe in a retrograde sense until the needle comes out.

– The purpose of this paper is to demonstrate the effectiveness of the medical device MD-Tissue, measuring objective parameters before, during and after the treatment of fifteen volunteers aged between 33 and 50 years.

In addition to the photographic documentation of the wrinkles with the photographic method Visioface® Quick, measurements of skin elasticity are performed with the elastomer.
All the equipment above described was kindly made available by BIOBASIC Europe Srl, Milan (Italy).

MATERIAL AND METHODS

– MD-Tissue

Fields of application known so far:
MD-Tissue is intended to improve the movement, helping to contain the physiological deterioration of joints and tissue and counterbalance the effects of a variety of causes including:
- Aging
- Postural defects
- Concomitant chronic diseases
- Trauma and injuries
- Polluting agents.

MD-Tissue is a medical device useful for facilitating mobility, counteracting the physiological aging of connective tissue, whose primary therapeutic treatment consists in the following functions:
1. Barrier
2. Lubricant
3. Mechanical support in the case pharmacological therapy.

– We recommend the use of MD-Tissue to be undertaken by qualified health professionals.

– Treatment protocol

Two treatments for the first 2 weeks, 1 treatment until improvement of symptoms (8-10 sessions on average).
If necessary, continue with one treatment every other week for a maximum of 10 sessions. Chronic pathologies: continue with 1 treatment a week for 1 month until improvement of symptoms, and subsequently 1 treatment a month.
- via intradermal injection: the area of application must be sterile; introduce the needle to a depth of 1-3 mm.
- via periarticular injection: the area of application must be sterile; introduce the needle in the proximity of the joint to a depth of 2-4 mm.

– Method of administration

For this use of the medical device, it is recommended to use the following materials and accessories:
- Material to ensure skin asepsis: dispo-

sable gloves, iodine based solution, alcoholic solution, sterile gauzes, ethyl chloride spray.
- Sterile needles (27G)
- Syringes (5 or 10 cc), depending on the amount of solution to be injected.

– Contraindications / Side Effects

No case of hypersensitivity to MD-Tissue has been reported.
Patients with known hypersensitivity to the component or the excipients must be previously undergo injecting test in the arm and kept under observation for one hour.

– Protocol applied for revitalization with MD-Tissue

Before proceeding with the treatment all the volunteers signed an informed consent. Then an allergological test with intracutaneous injection of a small amount of MD-Tissue was performed on all the volunteers in order to exclude a possible sensitization.

None of the 15 volunteers had any adverse reaction to MD-Tissue.

– After a phase of clinical observation lasting 30 minutes – which is generally sufficient to exclude immediate type I allergic reactions – basal measurements have been taken (time 0, T0) by performing a measurement of the skin elasticity of the **nasogenian fold** and a photograph of the face performed with the Visioscan® was also taken.
It was decided to apply a pattern that is frequently chosen in various protocols for anti-aging revitalization of the face. The injective treatment with MD-Tissue was performed once a week for 6 consecutive weeks.
At each session it was injected intradermally a 2ml vial of MD-Tissue in the nasogenian folds, following linearly the nasogenian fold with the tunneling technique.
Some volunteers have called for the application of an anesthetic cream prior to receiving this treatment.
The needle used was 27G.

After the 3rd session and prior to the 4th session, intermediate measurements (time 3 weeks, T3) were taken with photo-documentation and measurement of the elasticity, so to be able to better assess the progress of the treatment.
At the end of the treatment (after the 6th session) – 7 days after the last treatment – the latest measurements were carried out, always with photo-documentation and measurement of the elasticity.

– Self-evaluation form

At the end of the treatment, the volunteers filled out a self-evaluation form. The votes are comprised between 0 and 10, where 0 is equivalent to "not at all" and 10 to "very much." The evaluation is expressed spontaneously, in writing and kept reserved by the patient to avoid any influence from the doctor.

The questions that have been chosen for this experiment are the following:

1. To what extent do you think that the product reduces the visibility of the expression lines?
2. To what extent do you think that the product reduces the visibility of micro wrinkles?
3. To what extent do you think that your wrinkles are less deep?
4. To what extent do you think that the product increases skin elasticity?
5. To what extent do you think that the product increases your skin brightness?
6. To what extent do you think that your skin looks fresher / revitalized?
7. To what extent do you think that that the product increases your skin firmness?
8. To what extent do you think that the product increases your skin smoothness?
9. To what extent do you think that the product improves your skin texture?

Long term skin elasticity

Volunteer n.	t0	t 3 weeks	t 6 weeks
1	0,8123	0,8129	0,7092
2	0,6720	0,6786	0,7213
3	0,8785	0,8591	0,8088
4	0,6879	0,7143	0,7398
5	0,6906	0,7990	0,6931
6	0,7642	0,8412	0,8526
7	0,7500	0,8452	0,8400
8	0,7654	0,8168	0,8000
9	0,8265	0,8022	0,8387
10	0,8406	0,8300	0,8377
11	0,7721	0,8128	0,6633
12	0,7893	0,8084	0,8280
13	0,8150	0,7738	0,6606
14	0,7686	0,8254	0,6812
15	0,8030	0,8138	0,8067
Average	0,776	0,802	0,765
Dev. STD	0,0584572575	0,0480712665	0,0716924682
	Δ%	3,4	-1,3

TAB. 1
Long term skin elasticity.

10. To what extent do you think that your skin looks healthier?
11. To what extent do you think that the product gives your skin a "comfortable" feeling?

In the interpretation of the results it was decided to unify some votes to avoid data loss.
– The votes 9 and 10 are considered "very good"; 7 and 8 "good"; 6 "fair"; 3, 4 and 5 "poor".

– Skin elasticity

Skin elasticity is defined as the ability of the skin to stretch without breaking down, then returning to its original shape.
It has been measured with the elastomer (Cutometer® MPA 580, Courage-Khazaka Electronic GmbH, Koeln, Germany).
Applied to the skin, this device performs a suction of a part of the skin and the height reached by the aspirated layer refers to its degree of tensile distensibility; repeating several times the same maneuver, a further increase of skin distensibility can be observed – defined as tensile stretching, which is evaluated and recorded by the device.
The latest and most refined dermatological-physiological research could find that distensibility reflects the state of health of the collagen fibers of the dermis and that the recovery distensibility briefs about the conditions of the elastic fibers (4).

– Photographic documentation

The photographic documentation was performed with the computer system Visioface® Quick (full face photo analysis), CK electronic GmbH Koeln (Germany).

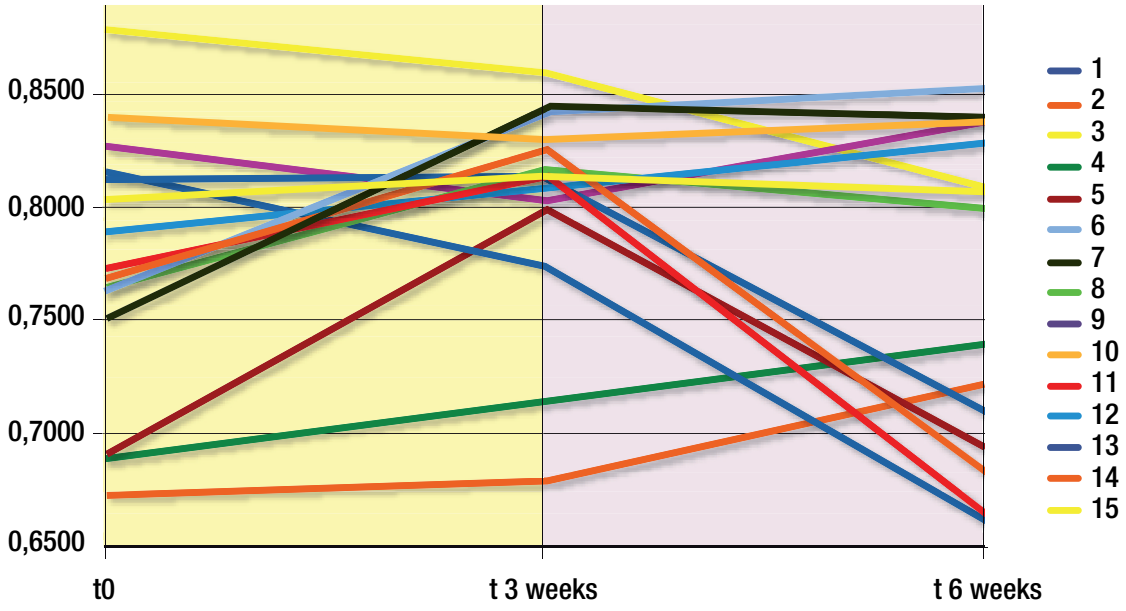
RESULTS

– Results of the measurement of skin elasticity

The results of the measurements of skin elasticity carried out on 15 volunteers at T0 (before treatment with revitalizing MD-Tissue) at T3 (1 week after the 3rd treatment, i.e before the 4th) and at T6 (1 week after the 6th and final treatment) are presented.
– The measurement was always performed on the nasogenian folds.
TAB. 1 lists all the numerical results of the 15 volunteers with their values at T0, T3 and T6.
– Overall, there was a slight increase in skin elasticity after 3 weeks of treatment, and after 6 weeks, the values return almost to baseline. The average of the values which initially was 0.776 increases on average to 0.802 after 3 weeks and then lowers again to 0.765.
After 3 weeks of treatment, 11 out of 15 volunteers (73.33%) show greater elasticity compared to the beginning.
Only 4 volunteers (number 3, 9, 10, 13) (26.33%) show a lowering of elasticity after the first three treatments.
After 6 weeks of treatment 9 voluntary out of 15 (60%) have greater elasticity than at the beginning, while 6 volunteers (number 1, 3, 10, 11, 13, 14) (40%) have a lowering of the elasticity under values of T0.
TAB. 2 represents graphically the results recorded by the volunteers (1-15).

– Results of photographic documentation Visioface® Quick

The volume and depth of wrinkles were studied with Visioface® Quick and the data processing was performed with the program Skin Surface Analyzer SSA.
From the front picture of the complete face it is chosen a small area located on the right or left nasogenian fold of each patient, this selected rectangular area corresponds to the "surface" of the wrinkle.
The "depth" of the wrinkle is measured in AU (Adimensional Unit).
It is a measurement scale created on a colorimetric basis to give depth to the selected area.



TAB. 2
Skin elasticity, graphical representation for each patient.

Wrinkle volume mm² X A.U.				
Volunteer n.	t0	t 3 weeks	t 6 weeks	%
1	0,4500	0,4500	0,3200	-28,9
2	0,2400	0,2000	0,2200	-8,3
3	0,1000	0,0900	0,0900	-10,0
4	0,1300	0,1600	0,1000	-23,1
5	0,8100	0,8500	0,7200	-11,1
6	0,2800	0,2300	0,2400	-14,3
7	0,2300	0,2300	0,1900	-17,4
8	0,2100	0,2500	0,2000	-4,8
9	0,1700	0,1900	0,1700	0,0
10	0,0800	0,0900	0,0800	0,0
11	0,3800	0,3600	0,3200	-15,8
12	0,1100	0,1000	0,1000	-9,1
13	0,5300	0,4000	0,4800	-9,4
14	0,2200	0,2400	0,2000	-9,1
15	0,1600	0,1500	0,1200	-25,0
Average	0,273	0,266	0,237	
Dev. STD	0,19722	0,19449	0,17182	
	Δ%	-2,7	-13,4	

TAB. 3
Wrinkle volume mm² 2 X A.U. with decrease percentage of each patient after 6-week treatment.

The "volume" of the wrinkle is the result of the following calculation:
Volume of the wrinkle (mm (2)) = AU x height (mm) x width (mm) x depth.

The volume of wrinkles was reduced by a total of 2.7% after 3 weeks and 13.4% after 6 weeks of treatment.
The values ranged from 0% to 28.9%.

– Results of self-assessment

Here below are shown the 11 questions along with the opinions expressed in votes and in percentage to which the 15 patients of the trial replied:

1. To what extent do you think that the product reduces the visibility of the expression lines?
   – The ability to reduce the visibility of the expression lines is considered by 80% of patients "good", by 6.67% "fair" and by 13.33% "poor".
2. To what extent do you think that the product reduces the visibility of micro wrinkles?
   – The ability to reduce the visibility of micro wrinkles is considered by 13.33% of patients "very good", by 53.33% "good", by 20% "fair" and by 13.33% "poor".
3. To what extent do you think that your wrinkles are less deep?
   – The perception of less deep wrinkles is for 6.67% of patients "very good", for 80% "good" and for 13.33% "poor".
4. To what extent do you think that the product increases the skin elasticity?
   – The increase in the skin elasticity is perceived by 86.67% of patients to be "good" and by 13.33% "fair".
5. To what extent do you feel that the product increases the brightness of your skin?
   – The increase in brightness is held "very good" by 13.33% of the patients, "good" by 66.67%, "fair" by 6.67% "fair" and "poor" by 13.33%.
6. To what extent do you think that your skin looks fresher / revitalized?
   – The perception of a fresh and revitalized skin is for 13.33% of patients "very good", for 66.67% "good" and for 20% "fair".
7. To what extent do you think that the product increases your skin firmness?
   – The increase in firmness is considered by 6.67% of patients "very good", by 73.33% "good" and by 20% "fair".
8. To what extent do you think that the product increases your skin smoothness?
   – The increase in smoothness is perceived by 6.67% of patients as "very good", by 60% "good" and by 33.33% "fair".
9. To what extent do you think that the product improves your skin texture?
   – The improvement in the skin texture is considered by 6.67% of patients "very good", by 46.67% "good" and by 46.67% "fair".
10. To what extent do you think that your skin looks healthier?
    – The perception of a healthier skin is for 6.67% of patients "very good", for 80% "good" and for 13.33% "fair".
11. To what extent do you think that the product gives your skin a

"comfortable" feeling?
– The perception of a sense of "comfort" is for 6.67% of patients "very good", for 73.33% "good", for 13.33% "fair" and for 6.67% "poor".

DISCUSSION

The aim of this study was to demonstrate the effectiveness of the medical device MD-Tissue as facial revitalizer.
15 patients – 33-50 years – were evaluated; first they underwent an allergy test with the provocation of a small intracutaneous wheal to exclude sensitization to the product.
MD-Tissue showed an acceptability of 100%, none of the patients experienced discomfort or side effects.
Consequently, they were administered weekly injections of MD-Tissue (2.0 ml), exclusively in the nasogenian folds. At the beginning of the treatment (T0), after 3 weeks (T3) and after 6 weeks (T6) a photographic documentation was performed using Visioface® Quick and the measurement of elasticity using the elastomer (Cutometer Courage - Khazaka).
At the end of the treatment the patients completed a self-evaluation questionnaire.

After 3 weeks of treatment the elasticity values showed an improvement of 73.33% and have achieved a total improvement of 3.4%; after 6 weeks of treatment they stabilized at 60%.

In order to achieve more indicative values, further measurements and – above all – a higher number of patients may be required.

However, the effect is present and elasticity in this work was higher after 3 weeks than after 6 weeks of treatment.

As for the photographic documentation obtained through the device Visioface® Quick and the data calculation achieved with the Skin Surface Analyzer SSA, results were highly positive.
The overall improvement of the patients, with a lowering of the wrinkle volume calculated by the Skin Surface Analyzer, was of -2.7% after 3 weeks and -13.4% after 6 weeks with peak improvements in the depth of wrinkles even reaching 28.9%.
– This very satisfactory result is also reflected in the data interpretation found in the patients' self-assessment questionnaire and in their happiness:

80% considered "**good**" the reduction of the visibility of the expression lines; they considered that the wrinkles on the face are less deep, and their skin healthier.
86, 67% considered "**good**" the increase in elasticity; **73.33%** judged as "**good**"; **6.67%** as "**very good**" the increase in the skin compactness; they also thought that the product gives a feeling of comfort.
66.67% considered "**good**" and **13.33%** "**very good**" the increase in skin brightness; they also thought the skin looked fresher and more revitalized.

In conclusion we can confirm that the medical device MD-Tissue revealed to be a reliable and safe product for the face revitalization.
– This can lead to several different uses in aesthetic medicine. The fluid texture of the product is definitely very suitable for the treatment of the neck, décolletage and back of the hands.
Face applications can include several techniques such as the treatment with micro wheals, injections in acupuncture points, eye zone and forehead rejuvenation. ■

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