

Evaluation of Safety and Efficacy of the Maximus™ System for Facial Wrinkles*

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ABSTRACT

Introduction: There is a growing demand for non-invasive methods with no down time and minimal risk for facial skin rejuvenation and treatment of wrinkles. The Maximus system, based on TriLipo technology, combines radiofrequency and Dynamic Muscle Activation (DMA). We evaluated the safety and efficacy of the Maximus™ system for the treatment of facial wrinkles. **Methods:** Twenty women received 8 weekly treatments for facial wrinkles using the Maximus system. Treatment efficacy was assessed by comparing pre- and post-treatment photographs, assessing skin characteristics using the 3D Visioscan system, assessing skin microtopography using the DUB ultrasonic scanning system, assessing microcirculation conditions of facial skin using Laser Doppler Flowmetry (LDF) and subjective evaluation of skin improvement. **Results:** No adverse events were observed. Following the treatments, positive changes in skin flakiness (scaliness), roughness, smoothness and wrinkles were demonstrated using Visioscan. A thickening of the epidermal-dermal layer and increased structural homogeneity were observed by ultrasound, hyperechogenicity was increased and areas of hypoechogenicity reduced. Microcirculation was improved, corresponding with a positive trend for improved skin characteristics. **Conclusions:** The Maximus system powered by the TriLipo technology is a non-invasive, effective, safe, and virtually painless treatment for reduction of wrinkles and facial skin rejuvenation.

Keywords: TriLipo; TriPollar; Radiofrequency; Dynamic Muscle Activation (DMA); Wrinkle Reduction; Anti-Aging; Skin Tightening; Collagen Remodeling; Skin Tonus

1. Introduction

Wrinkles are associated with ageing, as well as with exposure to ultraviolet light, hormonal status, smoking, and disease. The number of methods and technologies for treating wrinkles, tissue tightening, and facial skin rejuvenation have increased dramatically over recent years, as people have the demand for them. Non-ablative technologies, including laser treatments, ultrasound (US), electrical stimulation, and radiofrequency (RF) energy, have replaced ablative methods such as carbon dioxide and erbium: yttrium-aluminum-garnet lasers.

RF has been used for over one decade for facial tightening, and wrinkle reduction. Radiofrequency current penetrates deep dermal and subcutaneous fat layers; heat

generated through resistance of the tissue to the RF current shrinks layers of dermal collagen and increases the activity of fibroblast cells. The natural wound healing process follows the stimulation of new collagen formation [1,2]. RF is not affected by epidermal melanin as laser energy or other photo technologies are. Therefore it is of clinical benefit to all skin types, at lower and thus safer energy levels, without pain, and without injury to epidermal tissue.

The Apollo TriPollar™ technology (Pollogen, Israel) applies RF of 1 MHz, by means of multiple electrodes. RF-based systems have demonstrated effectiveness in treatment of striae distensae [3] and in the reduction of abdomen and thigh circumference and cellulite appearance [4,5].

TriLipo™ technology available in the Maximus™ system (Pollogen, Israel) is a novel technology that

*Safety and efficacy of TriLipo anti-aging treatment.

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combines focused, homogeneous RF TriPollar technology with low frequency Dynamic Muscle Activation (DMA). DMA improves microcirculation, venous return and lymphatic drainage, enhancing oxygenation and removal of waste products. The Maximus system's hand pieces are equipped with three or more electrodes and are used for skin thickness restoration, wrinkle profile reduction, and body shaping. The overall synergetic result of the TriLipo complex action consists of effective toning combined with skin tightening and rejuvenation due to remodeling of dermis and tightening of muscles and the SMAS layer (Superficial Muscular Aponeurotic System).

The goal of this study was to evaluate the safety and effectiveness of the Maximus system powered by the TriLipo technology, for skin rejuvenation and treatment of facial wrinkles. Both qualitative and quantitative measures were used for evaluation.

2. Methods

Women aged 35 - 65 were recruited for this study. Inclusion criteria comprised of: clinical symptoms of skin aging (such as decreased skin elasticity and turgor, dynamic and static wrinkles and folds, irregular skin texture), willingness to follow all recommendations and study instructions as explained by the investigators, including refraining from other anti-aging corrective treatments and rejuvenation techniques before and during the study period, and willingness to sign a written consent form for treatment and participation in the study.

Exclusion criteria included: simultaneous participation in another clinical research study, cardiac pacemakers or implanted defibrillators, a history of cancer, including malignant moles, diseases that could be activated by heat stimulation such as recurrent herpes simplex, impaired immune system caused by immunosuppressive diseases such as AIDS or the use of immunosuppressive medications, metallic implants in the treatment areas, and long-term steroid treatment.

The research was carried out in accordance with the ethical regulations of the local Helsinki committee.

2.1. Clinical Evaluation Methods

2.1.1. Safety Evaluation

Safety evaluation was obtained by analyzing recorded data of adverse events such as prolonged pain, excessive skin erythema or edema, signs of irritation or damage to natural skin texture, if occurred during the study treatments or reported at follow-up visits.

2.1.2. Skin Evaluation

Morphofunctional characteristics of the skin were assessed using noninvasive objective measurement skin di-

agnostic methods in the following standard test areas: 1) external periorbital area—along a horizontal line 1 cm from the lateral corner of the palpebral fissure; 2) zygomatic region—along the papillary line 1.5 cm from the eye rim; 3) “marionette lines” area—along a normal line 1.5 cm from the corner of the mouth, toward the lower jaw; 4) central area of the forehead—along the line dropping 1.5 cm from the inter-eyebrow space.

The morphofunctional condition of the skin was evaluated using the following noninvasive diagnostic techniques.

1) Visioscanning

For studying skin dynamic change as a result of the Maximus facial treatment, the Visioscan VC 98 system (Courage + Khazaka Electronic, Germany) was used. The protocol for Visioscan VC 98 was as follows: the selected skin area was monitored by a videocamera that transmitted images to the computer screen. The images were digitally processed and the following parameters were studied at standardized points: SEsc—scaliness; SEr—roughness; SEsm—smoothness; SEw—wrinkles. This test was conducted before the treatment, as well as 7 days and 1 month following the TriLipo treatment course. Simultaneously, the Soft Plus system (Callegary, Italy) using a microcamera, was used to obtain 3D-models of the test areas and perform data calculations to further evaluate skin dynamic change.

2) Ultrasonic Dermascanning

For noninvasive evaluation of skin microtopography, the DUB ultrasonic scanning system (Taberna Pro Medicum, Germany) was used. This scanner generates ultrasonic waves of 22 MHz frequency penetrating 7 - 8 mm. The rate of wave penetration depends on the thickness and elasticity of the media being tested, *i.e.* acoustical impedance (at ultrasonic frequencies) influences the velocity of wave propagation in tissues. The difference in acoustic impedance of adjacent areas determines echogenicity. DUB enables the selection and analysis of particular areas within set borders where size and echo-producing intensity of certain structures can be assessed.

Ultrasonic scanning was conducted before the treatment, 7 days later and 1 month following the last Maximus TriLipo tightening treatment. The data obtained were processed in accordance with parametric tests (Student's t-test) and non-parametric tests (Wilcoxon's signed rank paired samples test and the Mann-Whitney U test), using Statistica 6.0 (Statsoft, USA) software applications package for Windows. Results were considered to be statistically insignificant at $p \leq 0.05$.

3) Skin Microcirculation

Microcirculation condition of facial skin was evaluated before and after the TriLipo treatment course by Laser Doppler Flowmetry (LDF) using Laser Capillary Blood

Flow Analyzer LCBFA-01 (Lazma Scientific Production Enterprise Moscow), according to the manufacturer's protocol. LDF is a noninvasive, highly informative method for functional diagnostics of the skin microcirculation system. The LDF method is based on helium-neon laser light, which irradiates the test area and is reflected by moving blood particles (primarily by red blood cells). This causes a shift in radiation frequency (the Doppler Effect) which is proportional to the speed of particle flow. Radiation reflected from the red blood cells is directed over optical fiber and back to the device, where a signal proportional to the perfusion index of the tested area is analyzed. The laser beam penetrates skin as deep as 1.5 mm and provides information on blood flow in the superficial microvessels.

The measurement was carried out after patients rested for 20-minutes in the supine position. Patients stated that they avoided vasoactive medications, smoking, alcohol, coffee, strong tea, and extractive foods before the study commencement. The sensor was fixed on the skin surface and measurement recording time was 4 to 5 minutes.

Microcirculation index (MI) was used to measure changes in Microcirculation following treatment. The average microcirculation index (MI), in relative perfusion units, is dependent on the number and average speed of red blood cells that flow in capillaries and therefore reflects changes in microcirculation.

Measurements were carried out before the beginning of the treatment course, as well as 7 days and 1 month following the last TriLipo treatment session conducted with the Maximus system.

4) Subjective Satisfaction

Subjective grading of the skin condition was carried out by the patients immediately after the first treatment to evaluate immediate results, and at the last follow-up visit, to evaluate long term results. Patients graded their own improvement using various parameters such as: skin tonus, skin color heterogeneity and wrinkle sharpness. Patients' perceptions of the treatment were evaluated, including degree of comfort and unpleasant sensations felt during and after sessions.

2.2. Maximus Treatment Protocol

Eight TriLipo treatments using the Maximus system were conducted at 1-week intervals. Follow-up visits were conducted 1 week and 1 month after the last treatment.

Maximus TriLipo face treatments were carried out according to the treatment guidelines as specified in the device user manual. First a TriLipo RF only treatment of the full face was performed, followed by TriLipo DMA on the cheek area. 87% glycerin was applied on the treatment area before the treatment. A non-contact Infra-Red thermometer was used to measure Skin surface temperature. The temperature was recorded before and during the

RF treatment session, and maintained at up to 40°C - 42°C for the recommended treatment time.

3. Results

Twenty women with signs of aged skin participated in the study. Their average age was 43.

3.1. Safety Evaluation

No adverse events were detected. None of the 20 women complained of adverse results, either during or after completion of the TriLipo treatment. No allergic reactions were observed.

No negative sensations were experienced during the treatment. No signs of skin desquamation (scaling) or irritation were reported during the study period. Immediately after treatment, some of the patients reported transient erythema and slight edema that lasted several hours.

3.2. Skin Evaluation

The following before and after photos (**Figures 1-3**) demonstrate examples of clinical results following 8 face



Figure 1. A 37-year old female. Left—before treatment initiation; Right—at follow-up visit, one week after the last treatment.



Figure 2. A 45-year old female. Left—before treatment initiation; Right—at follow-up visit, one week after last treatment.

treatments. Results include: improvement of wrinkles appearance, skin tightening and definition of jaw line.

3.2.1. Visioscanning

Evaluation of skin characteristics was carried out on standardized check points. All parameters showed positive dynamics (see **Table 1**).

Analysis of the obtained data indicated statistically significant improvement for all measured skin characteristics after 8 treatments, with an additional improvement at 1 month follow-up. At the follow-up visit, measures demonstrated reduction in skin scaliness and roughness of over 40%, 83% increase in skin smoothness and 30% reduction in the appearance of wrinkles.

During the entire course of TriLipo therapy, researchers recorded a positive trend for skin quality, obvious facial oval shape correction, reduction in depth of wrinkles and folds and flattening of small lines.

In addition, after the Maximus TriLipo treatment, parameters describing color distribution homogeneity were significantly improved.

The Soft Plus microcamera system was used for Imaging and additional calculations of skin parameters. Measurements covered the horizontal wrinkles of forehead, “crow’s feet” wrinkles of eyes, and nasolabial folds. In general, data acquired by the Soft Plus microcamera correlates with visioscanning results. Skin characteristics improvements, *i.e.* smoothing of irregularities, reduction

in depth and length of wrinkles in the specific areas, as well as decreased diameter of pores were reported (**Figures 4-6**).

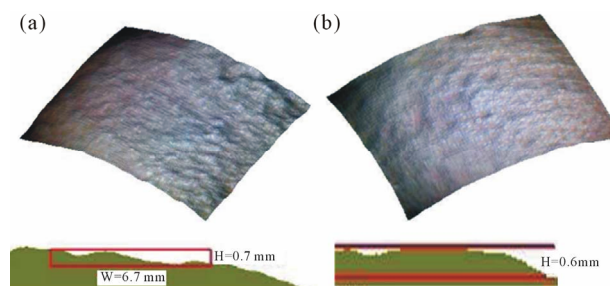


Figure 4. Imaging of a forehead horizontal wrinkle area (3D image of the area, sectional drawing of the skin test area). (a) Before the Maximus TriLipo treatment course; (b) 1 week after the Maximus TriLipo treatment course.

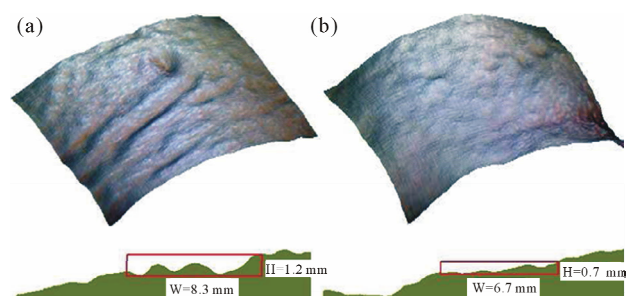


Figure 5. Imaging of the “crow’s feet” wrinkle area (3D image of the area, sectional drawing of the skin test area). (a) Before the Maximus TriLipo treatment course; (b) 1 week after the Maximus TriLipo treatment course.

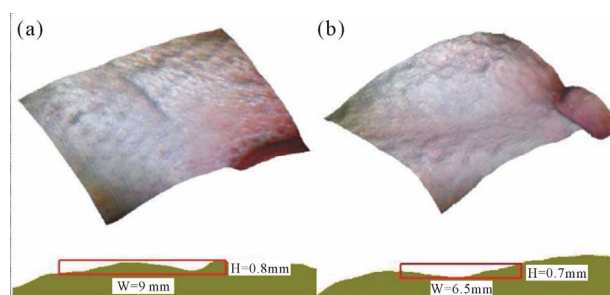


Figure 6. Imaging of the nasolabial fold triangular area (3D image of the area, sectional drawing of the skin test area). (a) Before the Maximus TriLipo treatment course; (b) 1 week after the Maximus TriLipo treatment course.



Figure 3. A 35-year old female. Left—before treatment initiation; Right—at follow-up visit, one week after the last treatment.

Table 1. Dynamics of skin profile average characteristics.

Average Value (Units), M ± m, p < 0.05												
SEsc—scaliness			SEr—roughness			SEsm—smoothness			SEw—wrinkles			
Before Treatment No. 1	After Treatment No. 8	One Month After Treatment No. 8	Before Treatment No. 1	After Treatment No. 8	One Month After Treatment No. 8	Before Treatment No. 1	After Treatment No. 8	One Month After Treatment No. 8	Before Treatment No. 1	After Treatment No. 8	One Month After Treatment No. 8	
Microrelief	0.63 ± 1.2	0.56 ± 0.30	0.35 ± 0.23	4.2 ± 1.5	3.8 ± 0.7	2.5 ± 0.8	23.9 ± 3.0	27.9 ± 6.2	43.8 ± 5.7	72.1 ± 4.0	67.2 ± 5.8	50.5 ± 4.2

3.2.2. Ultrasonic Dermascanning

Ultrasonic Dermascanning imaging was used for evaluation of changes in age-related skin parameters following the TriLipo treatment course. A US image of skin obtained before the TriLipo treatment course demonstrated the following characteristics: epidermal surface is relatively rugged, epidermis thickness is uneven ranging from 78 to 109 μm with variation index equal to 1.39 (relation of the maximal and the minimal thickness values to the length of the area), epidermis density is uneven ranging from 124 to 190 un., with variation index equal to 1.53 (maximal-to-minimal density ratio). The internal contour of epidermis is comparatively uneven. The epidermis-dermis junction boundary line has a tendency to flattening. Echo-signals pass from the skin surface to derma uninterrupted. Epidermis and dermis are clearly delimited. Subdermal Low-Echogenic Band (SLEB) is not detected. Thickness of dermis ranges from 734 μm to 813 μm and equals to 773.5 μm on average. Dermal echogenicity is not uniform. Echodensity of upper dermal layers equals to 25, echodensity of middle and lower dermal layers is up to 69, and the average echodensity of the entire area is 45. The dividing line between dermis and hypodermic tissue is clear. The average hypodermic tissue echodensity is 4 (**Figure 7(a)**). The TriLipo treatment course shows flattening of the epidermal profile, increasing of the average dermal thickness value from 773.5 μm to 1066 μm , increasing of the average dermal echodensity (echogenicity) from 45 to 51 and more even distribution of the echo-signal inside the dermis.

In general, according to the US-scanning data, skin characteristics show a positive trend of improvement after the Maximus TriLipo treatment course. The epider-

mal structure becomes more even, with reduced thinning areas, with thickness of up to 125 - 141 μm and variation index equals to 1.12. The internal contour of epidermis is even. The epidermis-dermis dividing line is clear. Epidermal density is moderately uneven—175 - 187 un., variation index—1.06 (highest-to-lowest density ratio). Surface-to-dermis echo-signal passage is uninterrupted. Subdermal Low-Echogenic Band (SLEB) is not detected. Thickness of dermis ranges from 1023 μm to 1109 μm and the average thickness is 1066 μm . Dermal echogenicity is uniform. Echodensity of upper dermal layers equals to 50, and 70 for lower dermal layers. Echodensity of the entire area is 51. The dividing line between dermis and hypodermic tissue is sharp. The average hypodermic tissue echodensity is 4.

In general, following the TriLipo treatments, the epidermal-dermal layer increased in thickness and improved in structural homogeneity, *i.e.* hyperechogenicity was increased and areas of hypoechogenicity were reduced, including compaction of the dermal papillary layer. **Table 2** demonstrates the significant increase of dermal-epidermal thickness and dermal density increase, which support skin functional improvement and demonstrates the efficiency of TriLipo RF technology combined with a Dynamic Muscle Activation (DMA) implemented in the Maximus system.

Results of the US measurements indicate noticeable improvements in skin characteristics, which can prove the positive effect of the RF technology on skin affected by age-related changes. One can say that this technology facilitates regeneration of thickness in deep skin layers due to stimulation of neocollagenesis.

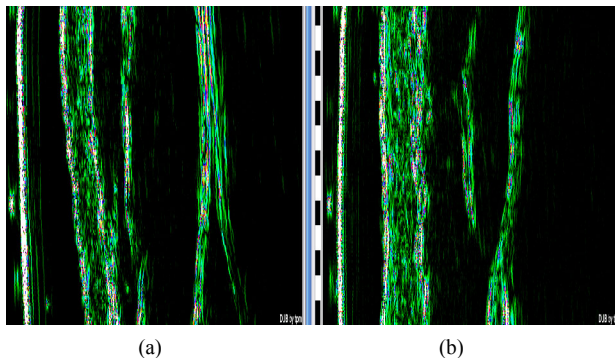


Figure 7. US skin image dynamics. (a) Before the Maximus TriLipo treatment course; (b) 1 week after the Maximus TriLipo treatment course.

3.2.3. Skin Microcirculation

Skin microcirculation measurements before treatment demonstrated average microcirculation index (MI) of 4.35 perfusion units.

The skin microhemodynamics data obtained following the TriLipo therapy course showed improvement in all microcirculation measures. Specifically, improved blood flow was demonstrated by improved tonus of arterioles, and increased average microcirculation index to 5.60 perfusion units.

Improvement of skin microcirculation after the TriLipo therapy treatment course corresponds with a positive trend of improvement in skin characteristics.

Table 2. Dynamics of average US skin image.

	Average Epidermal-Dermal Thickness, mm			Intensity (Density) of Dermal Structures, %		
	Before Treatment No. 1	One Week After Treatment No. 8	One Month After Treatment No. 8	Before Treatment No. 1	One Week After Treatment No. 8	One Month After Treatment No. 8
US Reading	1.30 \pm 0.16	1.6 \pm 0.22	1.75 \pm 0.12	3.8 \pm 0.51	4.0 \pm 1.2	5.5 \pm 1.15

3.2.4. Subjective Satisfaction

The patients reported an improvement of skin tonus, which they described as improved thickness and elasticity (lifting effect) of tissue. Most of them stated reductions in facial skin color irregularities and improvement of skin complexion. All the subjects noted that small wrinkles as well as deep folds had been smoothed to a certain extent. Patients reported a positive experience during the treatment, without pain, and described a warm relaxing sensation during and after the treatments.

4. Discussion

The Maximus system powered by the TriLipo technology demonstrated significant improvement in skin tonus, skin lift effect, reduction of sharpness of mimic and static wrinkles, and the improvement of facial skin color homogeneity, as measured by noninvasive quantitative methods including visioscanning, ultrasonic dermascanning and Laser Doppler Flowmetry (LDF).

Evaluations of efficacy of technologies for treating facial wrinkles generally rely on comparisons of photos taken before and after treatment.

Clinical improvements measurements have been demonstrated in other studies involving treatments using Tripollar technology. Kaplan and Gat [5] reported an increase of 49% in dermal thickness, focal thickening of collagen fibers and focal shrinkage of fat cells in abdominal areas treated with TriPollar technology compared to untreated areas. Boisnic and Branchet [6] reported a significant increase in collagen synthesis in ex vivo face lift fragments treated with Tripollar technology compared to controls. Levenberg [7] reported efficacy of treatment of wrinkles with the Apollo radiofrequency system, powered by TriPollar technology according to both objective and subjective criteria. Patients reported that the treatment was pleasant, similar to a warm massage, of the 37 patients treated for wrinkle or circumference reduction (buttocks, abdomen, thighs) in that study, 85.7% reported that the sensation was comfortable or extremely comfortable; the mean score was 4.1 on a scale of 5. Our findings of the efficacy of the Maximus system for treatment of facial wrinkles concur with these findings.

In addition, none of the five volunteers in Levenberg et al's study who agreed to have their blood tested for liver function and lipid profiles showed statistically significant changes between measures at baseline and after two body treatments [7].

Most of the patients in the current study rated an improvement following treatments with the Maximus system. The unique configuration of the TriPollar RF technology enables creating a high density energy field with reduced power consumption, this explains the pleasant

sensation reported by the patients, compared to the somewhat painful experience that accompanied treatments with earlier RF technology. In addition, we assume that the topical application of medical grade glycerin during treatment may have helped to prevent discomfort. The transient erythema and slight edema reported to have lasted for several hours in a number of patients may be explained by the heating of dermal tissues, and is thus an expected effect of the procedure. The absence of more serious adverse effects demonstrates the safety and tolerance of treatments.

No adverse events were observed in the current study, concurring with other studies of Tripollar technology [3-5,7].

Results of the quantitative measures used in this study demonstrate the safety and clinical benefit of the Maximus device powered by the TriLipo technology due to combined effects of TriLipo RF and TriLipo DMA, for skin rejuvenation and the treatment of facial wrinkles.

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