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TriLipo®- A Novel Non-Invasive Technology for Body Shaping and Facial Skin Tightening Using the Maximus™ System

Alex Levenberg, M.D., Physicians Center, Plastic Surgery Dept., Tel Aviv, Israel

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Abstract

Aesthetic procedures aiming at non-invasive localized fat reduction, circumference reduction, cellulite reduction and skin tightening are desired worldwide to substitute surgical, invasive procedures. Non-invasive treatments using RF, laser, IR light, ultrasound or muscle toning procedures are common practice but do not provide an optimal solution in terms of efficacy and drainage of the internally released fat. The TriLipo® technology simultaneously combines thermal RF effect for fat reduction and skin tightening with active muscles toning. The Maximus™ is a novel medical grade non-invasive system that uses the cutting edge TriLipo® technology for the purpose of body shaping by reducing and removing localized fat and tightening lax skin. In facial treatments, the Maximus™ offers unique local 'lifting' effect by combining dermal tightening and muscle toning. TriLipo® technology enables patients to benefit from visible immediate and long- term results using a simple "walk-in, walk-out" pleasant treatment.

Introduction

Excess localized fat, cellulite and lax skin are caused by the enlargement of hypodermal fat cells and the weakening and thinning of dermal connective tissue. Although significant clinical improvement may be achieved through surgical procedures, these are not without risk, and there is a growing demand for pain-free, non-invasive solutions that offer effective body and facial shaping. The mechanism of operation involves stimulating the natural metabolic processes and increasing collagen regeneration in a gradual, safe, painless 'lunch time' clinical procedure.

Several aesthetic treatment options are currently available for non-invasive fat reduction and skin tightening procedures. These include professional devices based on optical energy, Radio Frequency (RF) or ultrasound, devices based on vacuum, massage, or electrical muscle toning and devices that offer a combination of the above mentioned technologies.

The Maximus™, powered by the TriLipo® technology is a novel system for non-invasive body and facial shaping developed and marketed by Pollogen® Ltd. The system provides effective and fast fat reduction combined with collagen remodeling and skin tightening.

TriLipo® Technology for Body Shaping

TriLipo® technology uses a combination of focused TriLipo® RF energy and TriLipo® Dynamic Muscle Activation (DMA) energy which are delivered into the target tissue using a single applicator. The triple action of the TriLipo® technology consists of deep RF volumetric heating combined with internal muscle contraction and external mechanical force which together yield maximum fat removal and drainage as well as skin tightening. The RF energy generates heat through tissue resistance in both the dermal and subcutaneous layers. Selective and focused electro-heating of the skin stimulates and increases fat metabolism in the subcutaneous fat layer and collagen remodeling in the dermal layer.

In the subcutaneous fat layer, the thermal effect accelerates the natural fat metabolism process and the release of liquid fat from the fat cells into the extra-cellular matrix (Figure 1).

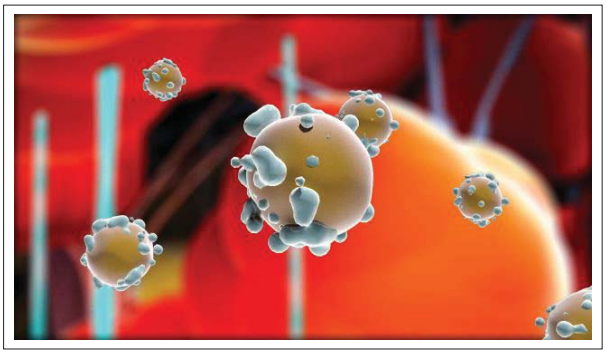

Figure 1: Liquefied fat released from fat cells

Drainage of the released liquid fat is accelerated by simultaneously applying internal and external pressure on the fat layer. Internally, Dynamic Muscle Activation (DMA) technology transmits energy pulses that stimulate the muscle layer causing the muscle to contract. This contraction elevates the muscle and pushes the fat layer up towards the surface. Simultaneously, the mechanical pressure of the applicator presses the skin from above. The combined internal and external pressure increases the effective penetration depth and drainage of the released liquid fat (Figure 2). Additionally, the TriLipo RF and TriLipo (DMA) effect cause the treatment area to heat homogeneously yielding accelerated blood and lymph circulation which optimizes tissue oxygenation and detoxification.

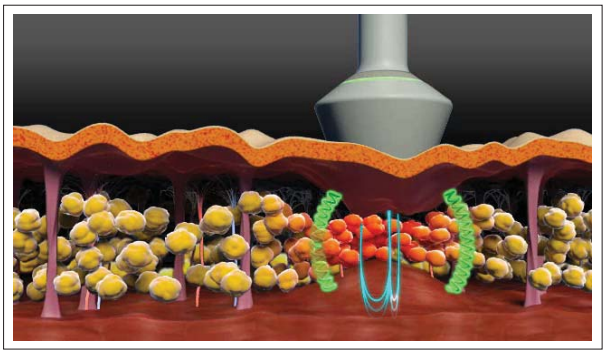

Figure 2: External and internal pressure yielding optimal drainage

In the dermal layer, focused RF energy heats the collagen fibers causing them to contract, resulting in immediate skin tightening and smoothening. In addition, fibroblasts' metabolism is accelerated leading to collagen regeneration and a long-term skin tightening and firming (Figure 3). The TriLipo triple action effect is visible

from the first treatment. Long-term body shaping is achieved within a short period of time by undergoing 4-6 treatments.

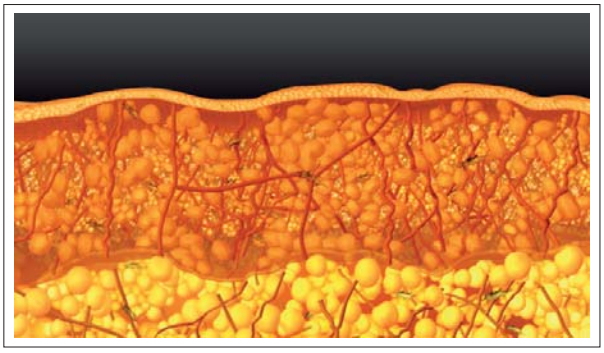

Figure 3: Collagen remodeling in the dermal layer leads to a smoother skin surface

TriLipo® for Facial Treatments

In facial regions, TriLipo creates a controlled thermal effect in the dermal layer which leads to new collagen production and tighter, smoother skin. The thermal effect is enhanced by the Dynamic Muscle Activation (DMA) in selected facial areas such as the cheeks and jaw line. The TriLipo muscle penetration depth is sufficient to affect the superficial muscular aponeurotic system (SMAS) layer. The SMAS layer is considered to be a key element in invasive facelift techniques, and using TriLipo technology, non-invasive toning of the SMAS can be achieved. The overall appearance of a facial tissue 'lifting' effect following TriLipo treatment results from the combination of dermal tightening and toning of the muscle and SMAS.

The Maximus™ System

The Maximus system, powered by the TriLipo® technology, is based on multiple electrodes that deliver TriLipo RF and TriLipo Dynamic Muscle Activation (DMA) simultaneously to the target tissues.

The TriLipo RF current is delivered at a frequency of 1 MHz and a maximum power of 50 watts to produce volumetric heating in the dermal and hypodermal layers.

The TriLipo® Dynamic Muscle Activation (DMA) uses multiple electrodes to deliver low frequency pulsed currents (LPC) to the underlying skin muscles. The system uses a biphasic mode with current regulation and is designed to limit combinations of current, pulse duration and frequency. Sophisticated algorithms control the TriLipo® energy output, providing maximum safety and efficacy.

The system consists of a main unit, three applicators, a foot switch and a bio-feedback control. The three ergonomically designed applicators differ in size and configuration to optimally accommodate treatment of different body and facial areas. Applicator No. 1 is indicated for the treatment of large body areas. Applicator No. 2 is indicated for the treatment of medium sized body areas and for facial areas. Applicator No. 3 is indicated for the treatment of very small and delicate facial areas.

The safety of the Maximus TriLipo® system is maximized by a few unique technical features and clinical protocols: multiple electrode modulation prohibits extended electrode heating and tissue over-heating at the electrode-tissue contact points; patented software limits the power density of the delivered energies; patient biofeedback automatically terminates energy delivery in cases of extreme discomfort; non-contact skin temperature monitoring during the treatment; a treatment protocol composed of continuous movement of the applicator on the treatment area; a multiple session routine.

The Maximus system is indicated for use in dermatologic procedures for non-invasive body and face shaping procedures, maximized by TriLipo® technology.

Clinical Overview

Different treatment programs are available for a wide variety of treatment areas. For body areas such as the abdomen, thighs and buttocks, a program combining the TriLipo RF and TriLipo Dynamic Muscle Activation (DMA) is recommended. For facial areas, a stepwise program starting with TriLipo RF and followed by Dynamic Muscle Activation (DMA) on the cheek area is suggested for optimal facial contouring results.

Default parameters are pre-programmed to facilitate treatment initiation. The parameters should be further adjusted by the operator from the user interface on the Main Unit according to the patient's reaction and skin tolerance. No active cooling of the electrodes or the skin is required.

Contraindications include pregnancy, any implantable electronic device, any active dermatological or vascular disorders and areas of sensory impairment such as in cases of nerve lesions and neuropathies.

Initial clinical evaluation of the new technology demonstrated safety and high efficacy in reducing localized fat deposits, circumference reduction and skin tightening.

Significant results were visible immediately after the first treatment. Long-term clinical results are achieved by undergoing relatively few treatments. Typically 4 treatments are suggested for long-term results (subject to the condition of the individual patient). Clinical results are demonstrated below in figures 5-8.

Figure 4: The Maximus™ system

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Summary

The increasing demand for non-invasive body shaping and facial skin tightening treatments that safely and effectively deliver measureable results has led to the development of combination treatment protocols. Combination modalities such as RF and ultrasound or other technologies, require alternating use between several devices or different applicators. These combination treatments are successful since clinical results are improved by the combination effect and sometimes the synergetic effect. However, the downside is the need for few devices and a complicated treatment protocol.

The TriLipo® technology provides a unique alternative for the treatment of localized fat deposits and skin tightening by simultaneously applying two types of energies delivered through a single applicator.

Maximus, powered by TriLipo® technology, is a safe and effective system for the treatment of excess localized fat, non-invasive body shaping and facial skin tightening. The clinical effect of the RF component, designed to produce volumetric heating of the skin for fat reduction and skin tightening, is enhanced by the lymphatic drainage mechanism that accelerates the removal of the released fat from the treatment area. The combined effect maximizes circulation and drainage and results in optimal body contouring.

Treatments are suitable for body and facial areas, in patients of all skin types. Following a treatment session patients may benefit from measurable and visible results.

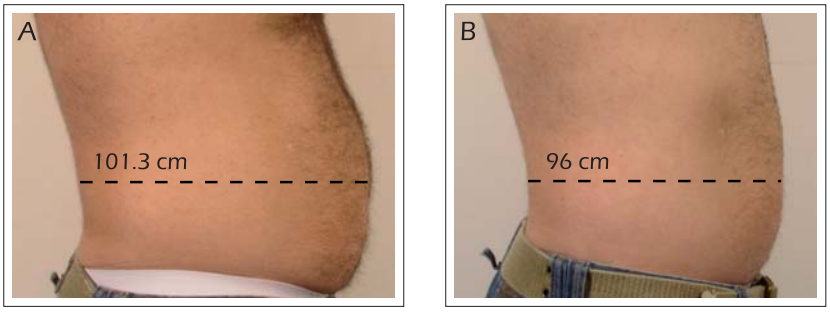

Figure 5: Male abdomen post 6 treatments: A) Before B) Post 6 treatments, total reduction of 5.3 cm.
Photos courtesy of Cruzy Salazar, M.D, Pollogen in-house

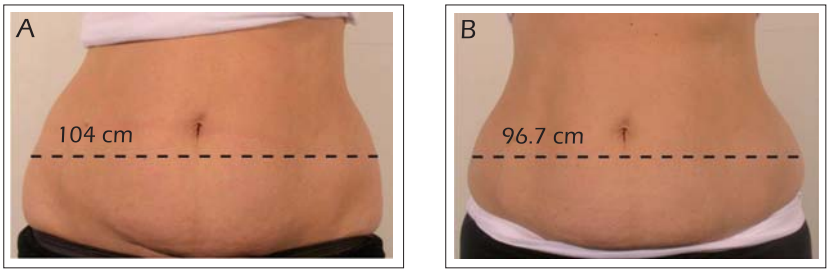

Figure 6: Female 7 months post pregnancy. A) Before B) After 3 treatments, reduction of 7.3 cm.
Photos courtesy of Cruzy Salazar, M.D, Pollogen in-house

Figure 7: Facial skin tightening. A) Before B) After 5 treatments.
Tightening effect on cheek area is visible.
Photos courtesy of Cruzy Salazar, M.D, Pollogen in-house

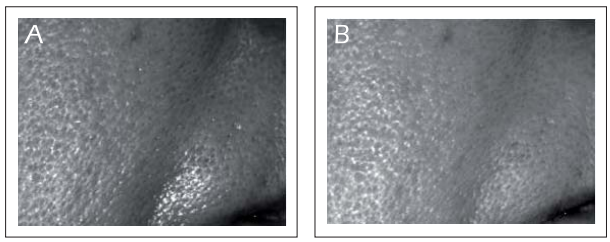

Figure 8: Primos 3D analysis of facial results.
A) Nasolabial fold before treatment
B) Fold after 2 treatments