

27 Mar 2019
12:45 am

GIMIV
MEDICAL INNOVATION



Needle
Shaping

CARBO
MAX®

O.F.F.



ECRON



WORKLINE

THE PERFECT
SINERGY OF
TECHNOLOGIES FOR
MINIMALLY INVASIVE
TREATMENTS
IN AESTHETIC
MEDICINE

by

GIMIV

SOFT SURGERY

Soft Surgery - minimally invasive surgery is a treatment method performed through GMV medical devices as an **alternative to classic surgery**. Soft Surgery has been designed for all those who want to correct skin blemishes **without resorting to surgery and / or pharmacological treatments**: the results obtained are absolutely comparable to traditional methods for numerous treatments.

The key concept of today's aesthetic treatments is "naturalness of facial expression". It is no longer the amazement with flashy treatments that require patients, but to show their beauty while maintaining their identity and harmony of features.



+ 200% Increase of minimally-invasive cosmetic procedures since 2000 in USA



Minimally-invasive cosmetic procedures grew at a slightly higher rate than surgical procedures.

Source: American Society of Plastic Surgeons (2017)

SCIENTIFIC RATIONALE

“Carboxytherapy is an effective technique of treatment of cellulite in the buttocks region and posterior thighs of healthy women.”

[Ramalho Pianez L, Silva Custódio F, Michelini Guidi R, Nunes de Freitas J, Sant’Ana E. Effectiveness of carboxytherapy in the treatment of cellulite in healthy women: a pilot study. Clinical, Cosmetic and Investigational Dermatology]

“The two innovative methods (Needle Shaping, O.F.F.) open up new horizons in aesthetic medicine and bloodless surgery... Thanks to their excellent results, the patient recommends the treatments in his wider social circle and do not hesitate to make other cosmetic procedures (non surgical) because he/She does not face the fear of surgery.”

[Tsioumas G S, Choroizidis I, Papapostolou A. The Efficiency Of Vibrance (Needle Shaping) And O.F.F (Non Surgical Dermal Ablative Treatment) On Body Reshaping. Pinnacle Medicine & Medical Sciences]

“Unlike contemporary physical methods that affect all tissue components, Pulsed Electric Fields (PEF) is an intervention at the cellular level, which precisely targets cell membranes through electroporation without affecting the extracellular matrix architecture”

[Golberg A, et al. Skin Rejuvenation with Non-Invasive Pulsed Electric Fields. Scientific Reports]

“The technique of manual lymphatic drainage (MLD) is one of the main pillars of the treatment of lymphedema, because its movements help lymphatic circulation”

[Schonvvetter B, Soares JLM, Bagatin E. Longitudinal evaluation of manual lymphatic drainage for the treatment of gynoid lipodystrophy. An Bras Dermatol.]

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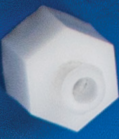
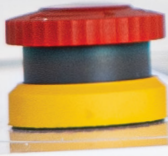


Needle
Shaping

CARBO
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Needle Shaping

What is Needle Shaping

It is a microsurgical technique that allows to progressively increase the volume of lips, cheekbones and depressed scars **without injecting any type of material or drug.**

How does it work

It is a **microscopic tissue transplant for traction** (autografting) performed using a thin needle, similar to those used for acupuncture, through which a current is delivered with the possibility to modify the fundamental parameters (pulse width and pulse repetition rate).

The mixed currents, enhanced by their **synergistic action**, adjusted to an intensity that is not perceived by the patient except in certain particularly sensitive points, slightly dehydrate the elastic fibers of the dermis and make them hook to the needle and mainly that they tie together making a lasting effect.

Then they wrap themselves with extreme delicacy until they get a sort of spindle of autologous material that is invisible to the movement of the needle. The traction exerted must be such as to obtain a certain volume of fibers without ever tearing them. The liquids are eliminated osmotically by saline deprivation mediated by currents, to avoid the unrolling of fibers and collagen.



Applications

- Correction of facial hypovolumeters
- Increasing lip volume
- Correction of expression lines
- Scars treatment
- Saline deprivation of the subcutaneous tissue
- Collagen regeneration
- Biostimulation of the face
- Autologous virtual traction lines



What is O.F.F.

Fractional Flow Waves are a technology for the **reduction of localized fat deposits** on face and body and the elimination of capillaries, angiomas and superficial telangiectasias. They use a fixed frequency sine wave, with a fractionable emission flow that drastically reduces the sensation of heat received by the patient and maximizes its effectiveness in the application.

How does it work

Through O.F.F. a **sine wave is produced at a fixed frequency** of about 1230kHz with fractionable flow, ie an active medical device, which is able to transfer concentrated energy through a handpiece equipped with sterile and disposable needle. These waves will be transformed into fractional heat by Joule effect which can be used for non-invasive selective micro lipolysis treatments - directed into the subcutaneous adipose district - and the removal of small angiomas, capillaries and telangiectasias. These sine waves are programmable so as to obtain different results on different tissues also depending on the application method.



Applications

- Superficial vascular lesions: angiomas, capillaries and telangiectasias.
- Extremely selective microlipoplasty with elimination of adipose tissue through fragmented destruction by fractional hyperthermia. This selective distribution of heat that does not involve the superficial cutaneous tissues, allows to treat limited areas of adipose accumulations, such as those of the underneath, of the perimandibular subcutaneous and of other body districts (under gluteal, trochanter, abdomen) obtaining a harmonizing effect without leaving steps or retracting scars.



What is CARBOMAX

This technology uses carbon dioxide in the gaseous state for therapeutic purposes.

Carboxytherapy acts at the level of microcirculation.

The aim is to **rebalance the altered microcirculation**, mainly interfering with the factors that regulate local blood flow in the short term and consequently favoring an increase in the speed and extent of blood flow in the microcirculation. The effects translate into better tissue oxygenation and consequently, an enhancement of cellular metabolism; with an increased supply and release of oxygen the oxidative processes of fatty acids are favored. Furthermore, an increase in local tissue blood flow results in an increase in local tissue metabolism with a greater energy demand on the part of the adipose tissue involved, therefore with greater stimulation of lipolysis.

How does it work

The lipolytic action of carboxytherapy is mainly linked to **three mechanisms**:

- Increased local tissue blood flow;
- Receptor activation;
- Amplification of the Bohr effect and the Haldane effect.

It is a safe treatment, because the gas is non-toxic and cannot cause embolism. Once administered it is eliminated from the lungs and kidneys.

Innovations included in our technology:

- Electronic CO₂ flow controller
- Electronic pressure control - LIVE visual feedback of the EFFECTIVE CO₂ supplied
- Gas heater before the erogation
- LIVE pressure measure of the CO₂ tank
- Double CO₂ supply modality: flow or pressure control
- Simultaneous Multi-insufflation



Applications

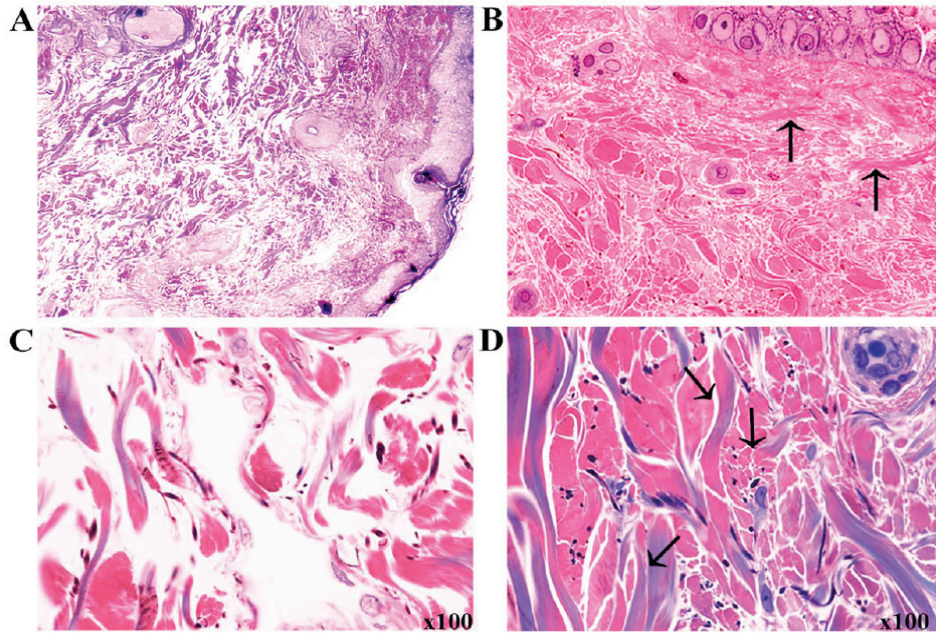
This biochemical mechanism is applied in numerous specific therapeutic indications:

- circulatory and draining;
- lipolytic: the increase of oxygen released at the tissue level, causes oxidation of the fatty acids that break up and enter the Krebs cycle (district lipolysis);
- localized adiposity, the reductive effect of the diameters of the treated areas is important. The effects are noticeable on recent cellulite.
- toning: the increase in the percentage of oxygen in the tissues improves skin elasticity and therefore rejuvenation of the dermis. A toning of the skin of the face and neck is obtained with the possibility of treatment on the body for an improvement of the body contouring.

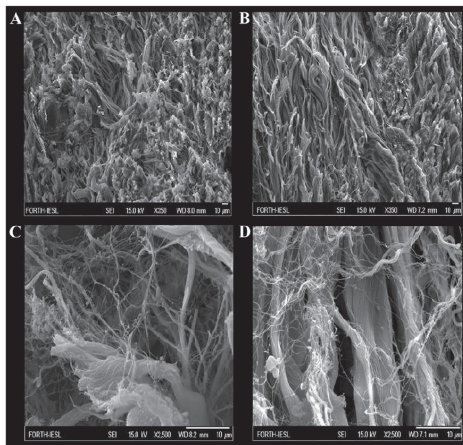
RESULTS



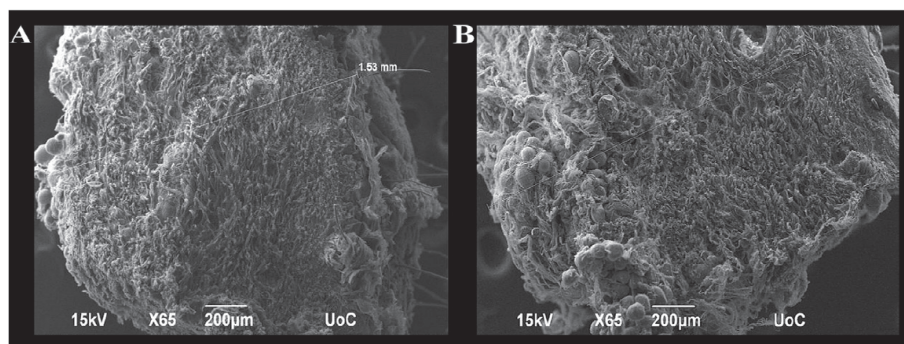
Histological & Microscopical Evaluation¹



Histological evaluation by light microscopy of biopsies taken before and after needle shaping treatment. (A and C) Skin samples before (panel A, $\times 25$ magnification; panel C, $\times 100$ magnification) and (B and D) after needle shaping treatment (panel B, $\times 25$ magnification; panel D, $\times 100$ magnification) were stained with trichrome staining (most significant micrographs are shown). Changes in matrix organization are indicated by arrows. The images depicting tissues after the treatment (B and D) demonstrated a more compact dermis, with a healthy matrix network. Specifically, collagen fibers are larger and thicker with a more ordered alignment of fibers of the treated skin as compared to the images obtained before treatment (A and C).



Evaluation by scanning electron microscopy (SEM). Skin specimens were coated with gold and viewed using a scanning electron microscope at different magnifications before (A and C) and after (B and D) needle shaping treatment were (most significant micrographs shown).



Evaluation by scanning electron microscopy (SEM) (most significant micrographs are shown). Skin specimens coated with gold (A) before and (B) after needle shaping treatment were viewed using a scanning electron microscope.

A UNIQUE MEDICAL DEVICE THAT COMBINES THE PRINCIPLES OF PHYSICS AND BIOLOGY TO PROVIDE THE DOCTOR WITH ALL THE INSTRUMENTS FOR NON-INVASIVE SURGERY TREATMENTS

- 2 technologies based on the fundamentals of electrophysiology

- 1 technology that uses biochemical mechanisms

- Scientifically validated technologies^{1,2} and tested over the years on hundreds of patients with excellent results

- Immediate and progressive results over time

[1] Sifaki M, Calina D, Oana Docea A, Tsioumas S, Katsarou MS, Papadogiorgaki S, Fragkiadaki P, Branisteanu DE, Kouskoukis K, Tsiaoussis J, Spandidos DA. "A novel approach regarding the anti-aging of facial skin through collagen reorganization". *Experimental And Therapeutic Medicine*, 2020.

[2] Tsioumas G, Sotiris, Vlachodimitropoulos Dimitris, Goutas N. *Clinical And Histological Presentation After Plexr Application, Needle Shaping (Vibrance) And O.F.F. Pinnacle Medicine & Medical Sciences*, 2015

[3] Tsioumas G, Sotirios, Combination of Autologous Treatments for Non-Invasive Blepharoplasty and Non-Surgical Full Face Lift. *J Clin Exp Dermatol Res* 2017, 8:5

GMV

PLASMA PIONEERS IN AESTHETIC MEDICINE ALWAYS ON TOP IN THE DEVELOPMENT OF NEW TECHNOLOGIES

GMV is famous all over the world for introducing plasma technology in aesthetic medicine. The Plexr plasma medical device was the first device to be used for minimally invasive procedures. With over ten years of scientific research, Plexr has proven to be safe for clinical use.

GMV has always been dedicated to the development of new technologies at the service of doctors and patients.

- ISO 9001 and EN ISO 13485 quality management certifications
- Devices, certified according to Directive 93/42 / EEC for medical devices
- Creation of devices entirely in-house, from the idea and the prototype, to production and sales
- Constant technical and training assistance for doctors

Technical Specifications

| TECHNOLOGY | | OUTPUT | |
|----------------|-------------------|-----------|-------------------------------------|
| Name | Waveform Measured | Frequency | Max power Flow Rate/ Pressure |
| OFF | Sinusoidal | 1.2 MHz | 30W |
| Needle Shaping | Costant | 0 | 1 W |
| | Square wave | 4 Hz | 1 W |
| | Pulses | 0-100 Hz | 1 W |
| Carbomax | CO2 Flow Rate | - | 20-200cc/min |

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ISO 9001:2015
ISO 13485:2016