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OOO “MEDI SPA GROUP”

General Director
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Results of the clinical trials of the new technology for connective tissue micro alveolar stimulation: ICOONE-H,

ICOONE-H **(translated in Italian as «ICONA»)**, is a newly designed electro-mechanical medical instrument for a fractionated massage which effects the collagen and elastin fibres of connective tissue. The mechanism involves a mechanical friction by rotating and aspirating rollers and an aspiration vacuum in the interstitial spaces of the connective tissue. The negative frequency of aspiration creates an action mechanism of mechanical stress of the micro alveolar vacuoles formed in between the collagen fibres of the mesenchymal tissue, which removes the excess interstitial liquid so as to create a «draining» of the lymphatic system.

The revolutionary **ICOONE-H Roboderm** patented method is the only technology able to deliver **Multi Micro Alveolar Stimulation.** The device softly traps the skin located under the connective tissue, squeezing it. This happens not only between the two rollers but also inside the rollers themselves. In a square decimetre of the body 1180 **microsimulations are produced!** This technology is able to provide physiological benefits to the body.

The headpieces softly catch the skin and induce motility of the dermal and subcutaneous vascular channels. We can identify three different actions: draining provoked by the pressure of the rollers, skin stretching and connective fibrils dynamic stimulation in the central area, and reflex neurovascular motility triggered by the oscillatory movements of the machine where treatment is needed.

Thanks to its special mechanical energy transmission, ICOONE-H is able to stimulate each layer of the skin: epidermis, superficial dermis and deep dermis. Its action is more effective on fat and muscular tissue. Due to a consistent effect of rhythmic negative pressure on certain areas of the skin the device affects blood pulsation and naturally modulates the fine endings of the sympathetic and parasympathetic nervous system. Such is the reflexology approach, which is very effective for its mechanical squeezing and for the drainage of the lymph and of interstitial fluid due to vasomotor vascular response. This strategy can be used, not only for cosmetic skin improvement but also for musculoskeletal and visceral disorders.

All mechanical physiotherapy instruments, create a rhythmic superficial-to-deep massaging that reproduces the flexible movement of the human hand as much as possible, inducing an active or passive skin structures stimulation. The human hand, however, doesn't have purely mechanical functions as are vacuum suction and rhythmic pressure. In fact, the human hand can pinch, lift and stretch skin, but it does not have a fractionated pulsatile action. Along with the movement of the two twin rollers, this action has a positive effect on the interstitial fluid dynamics. The rotating movement of the hand pieces on the skin creates a rubbing, that compared with hand massaging, is extremely positive; in particular when the rotating movement of the rollers creates a vacuum therapy suction and therefore a clearing of the gravity-pooled interstitial lymphatic fluid.

An interesting feature of ICOONE-H is the ability to actively aspirate the skin thanks to the rotation of the rollers with micro-holes and a central chamber between them (see diagram) and is fundamental for the effectiveness of treatment. The new combined suction-pressing effect is a distinctive feature of the device. The aspirating effect of the handpiece creates such a traction on the elastic-collagen matrix of the dermis and the subcutaneous tissue so that it results in a much more gradual and broader coverage. This definitely increases lymphatic and micro-circulation flow efficacy along the work axis of ICOONE.

ICOONE offers 16 medical programmes and 20 beauty programmes, which if combined can be adapted to any kind of patient and his/her needs.

At the beginning, this device was used in aesthetic medicine but after various treatments, positive medical effects were also noticed. Therefore numerous clinical studies were carried out and all of them have proved the effectiveness and safety of the new device. The following programmes have been developed:

1. Beauty programmes:

◻ Cellulite (stage 1-4)

◻ Procedures for décolleté skin rejuvenation

◻ Circulatory disorders

◻ Relaxation

◻ Contour Formation of face and body

◻ Reduction of wrinkles

◻ Lymphatic drainage

◻ Reduction of localized fat deposits

◻ Stimulation of elastin formation

◻ Skin rejuvenation

◻ Stimulating of fibroblasts

ICOONE-H is used not only in cosmetology and aesthetic medicine, but also in the treatment of specific skin diseases, with a tendency of connective tissue to form keloid or hypertrophic scars, in the treatment of edema, caused by venous insufficiency and lymphostasis, by trophic disorders. There is also a positive effect in the treatment of hypotension of the intestine, due to the stimulation of the mechano-receptors of the skin.

2. Medical programmes:

◻ General reinforcement

◻ Cicatricial changes after burns

◻ Vascular disease

◻ Hypotonia of the digestive tract

◻ Pain syndromes with dermatitis

◻ Pain with muscle tension

◻ Disturbances of microcirculation

◻ Venous insufficiency

◻ Edema Cellulite

◻ Swelling of the lower extremities

□ Cicatricial changes of tissues condition after endoprosthetics

□ Before and after liposuction

□ Tendinopathy

□ Myalgia

3. Sport programmes:

□ Consequences of damage

□ Hematomas

□ Extensions

□ Muscle injuries

□ Muscle pain

□ Muscle cramps

□ Muscle spasms

□ Warm up the muscles

□ Rehabilitation

To assess the effectiveness of lymph drainage restoration, a group of patients with chronic venous insufficiency was examined.

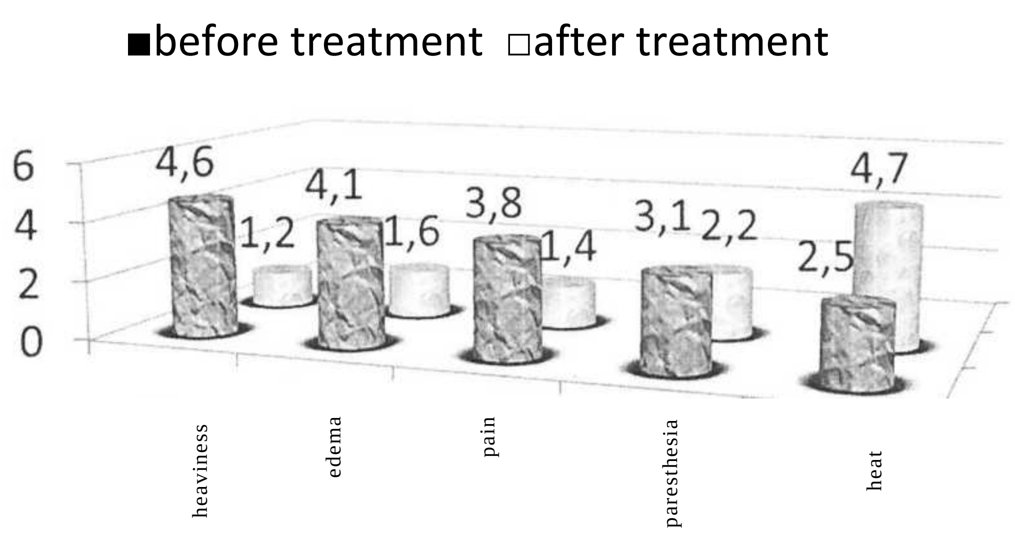
Material and methods of the study: 46 patients with established diagnosis of CVI (Chronic Venous Insufficency) st. I-III without profound trophic changes Exclusion criteria were: severe cardiovascular pathology, haemorrhagic diathesis, systemic connective tissue diseases, exudative immune-allergic skin diseases, severe kidney failure, thrombosis of the vessels of the lower extremities, reception of indirect anticoagulants, change in basic drug therapy during the last 4 weeks. Of the 46 examined patients, 15 were men and 31 women. The average age of the patients was 64. For clinical-instrumental examination of patients the following methods were used:

- Doppler Ultrasonography of the veins of the lower extremities and soft tissues of the lower leg
- Measuring the volume of the lower extremities at the level of the lower leg, ankle joint
    - Subjective assessment of CVI symptoms on a 5-point scale

The treatment was carried out on the device ICOONE-H programme combining two consecutive protocols: the first phase of the action with a power of 3-4 units and a frequency of 11Hz and a rhythm of the wave of 10 Ip - for 10 min on each limb, daily for 5 days. Then the second phase of the action with a power of 4-5 units, a frequency of *2 Hz and* a rhythm of the wave 4 Ip.

Results: After treatment, patients noted an improvement in the general condition and a decrease in signs of CVI, namely: a decrease in severity to a feeling of lightness in the legs when walking, a decrease in swelling, a reduction of pain in the legs, numbness in the feet and cramps in the calf muscles, an increase in heat in the feet (Figure 1).

Figure:1



The following results were revealed in clinical and instrumental survey methods:

- Thickness of subcutaneous fatty tissue (edema, lymphostasis) average.

<u>Right lower leg, thickness of subcutaneous fat tissue before treatment:</u>

The middle third of the lower leg: 9.9 ± 4.5; Lower third of lower leg: 8,8 ± 3,3; At the foot level: 3.7 ± 2.6.

<u>Right lower leg, thickness of subcutaneous fat after treatment:</u>

Middle third of lower leg: 9.2 ± 4.0; Lower third of lower leg: 8.3 ± 3.7; At the foot level: 3.1 ± 2.1

Statistically significant differences in the thickness of subcutaneous adipose tissue in the middle third of the lower leg, $p < 0.05$.

<u>Left lower leg, thickness of subcutaneous fat tissue before treatment.</u>

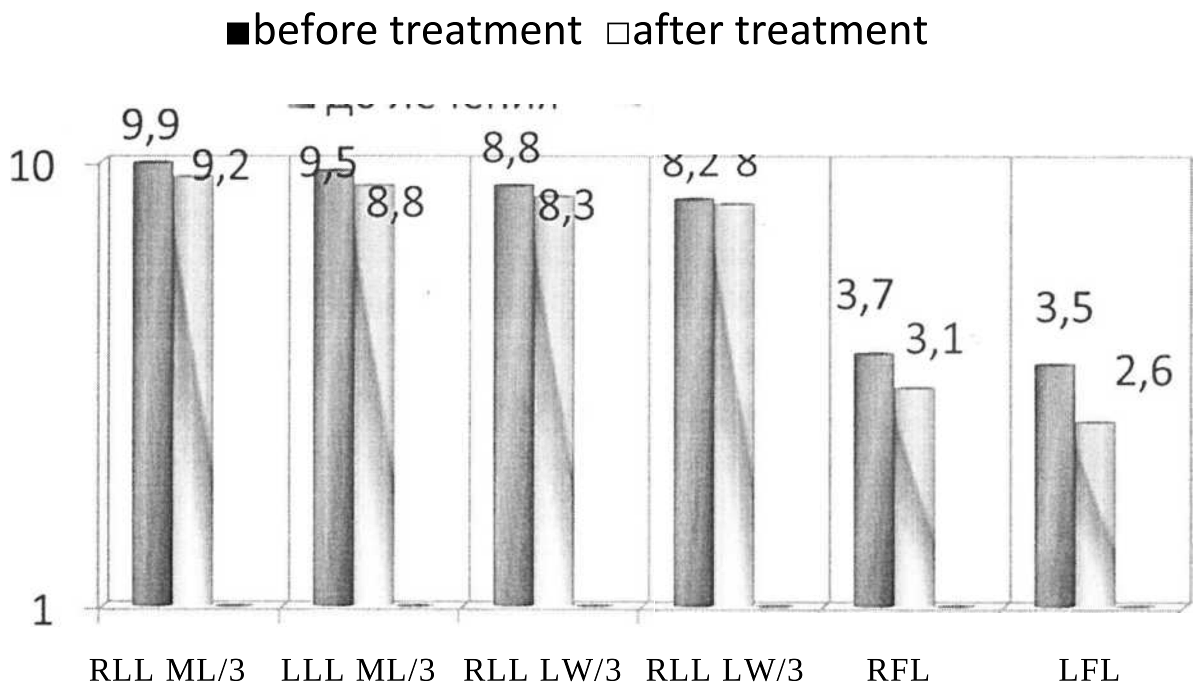
The middle third of the lower leg: 9.5 ± 3.4; Lower third of lower leg: 8.2 ± 3.6; At the foot level: 3.5 ± 1.6.

<u>Left shin, thickness of subcutaneous fat tissue after treatment.</u>

The middle third of the lower leg: 8,8 ± 4,2; Lower third of lower leg: 8.0 ± 3.3; At the foot level: 2.6 ± 1.0 (Figure 2).

Statistically significant differences in the thickness of subcutaneous adipose tissue in the middle third of the shin and at the level of the foot, $p < 0.05$.

Figure 2



<u>The diameter of the right lower leg before treatment.</u>

Middle third of lower leg: 52.8 ± 8.4; Lower third of lower leg: 38.6 ± 3.6; At the level of the foot: 23.5 ± 2.6.

<u>The diameter of the right lower leg after treatment</u>

The middle third of the lower leg: 50.5 ± 9.6; Lower third of the lower leg : 37.3 ± 3.5; At the foot level: 22.3 ± 2.0.

Statistically significant differences in the thickness of subcutaneous adipose tissue in the middle third of the shin and at the level of the foot, $p < 0.05$.

<u>The diameter of the left lower leg before treatment.</u>

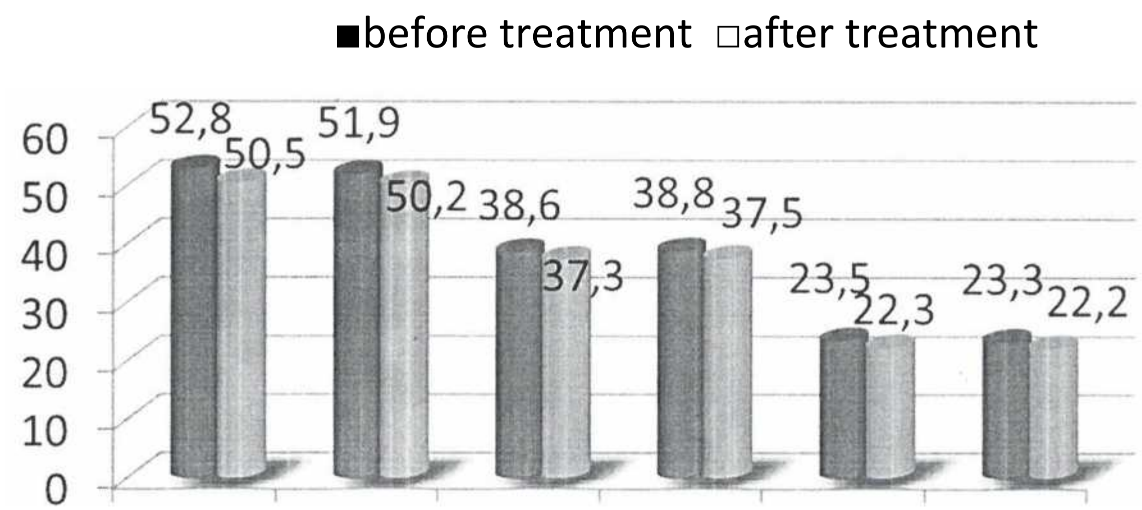
The middle third of the lower leg: 51.9 ± 7.9; Lower third of the lower leg: 38.8 ± 3.5; At the level of the foot: 23.3 ± 2.2.

<u>The diameter of the left lower leg after treatment.</u>

The middle third of the lower leg: 50.2 ± 9.8; Lower third of the lower leg: 37.5 ± 3.8; At the foot level: 22.2 ± 1.6 (Figure 3).

Statistically significant differences in the thickness of subcutaneous fat in the lower third of the lower leg and at the level of the foot, $p < 0,05$.

Figure 3



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Conclusions. Thus, the results of our research allow us to say that the electromechanical vacuum medical apparatus of the last generation ICOONE - H showed high efficiency and safety in the treatment of chronic venous insufficiency. The device has good tolerability and a wide range of indications for daily use; it is convenient in operation. In addition, according to the results of the study, there were no side effects at given regimes.

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