

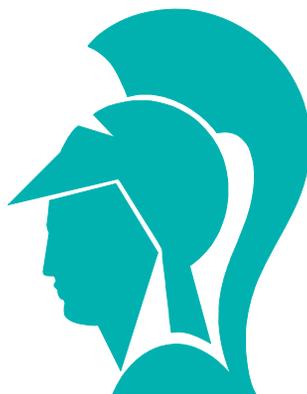
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**INTERMITTENT MICROALVEOLAR STROMAL
STIMULATION THERAPY: LOWER LEGS FUNCTIONAL
AND COSMETIC RESHAPING BY LYMPHO-VEINOUS
NETWORK ACTIVATION**

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E D I Z I O N I · M I N E R V A · M E D I C A

ORIGINAL ARTICLE

Intermittent microalveolar stromal stimulation therapy: lower legs functional and cosmetic reshaping by lympho-venous network activation

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ABSTRACT

BACKGROUND: The multi-micro stromal stimulation system electromedical device is effective upon interstitial subdermal and subcutaneous spaces re-balancing elastic fibers, fat cells and microareolar spaces of mesenchyme to promote body remodeling. Our spontaneous and anecdotal study investigates the benefits of microalveolar stimulation treatment in feet, ankles and legs remodeling in patients affected by mild lymphedema of calves and legs.

METHODS: Twenty-five female patients were recruited in this study. icoone[®] robotized device was used for its peculiar skin suction pressing and rotating function. The circumferences of foot, ankle and leg were measured before starting the treatment, after 1 month of treatment, and 1 month after the interruption. In addition, skin parameters (elasticity and dermis embedding) were analyzed before and at the end of the treatment. Finally, a self-reported questionnaire was administered in order to assess the benefits of icoone[®] treatment.

RESULTS: A significant reduction of foot, ankle and leg circumference was observed after 1 month (P=0.019; P=0.001; P=0.002 respectively). A significant correlation was present between the BMI and leg circumference measured before starting the treatment (P=0.002). A significant increase of skin elasticity (P=0.01) and reduction of skin dermis embedding (P=0.001) were registered after 1 month. Patients reported subjective legs lightness feelings, enhanced micturition, sparkling energy and wellbeing after each session. A more appealing esthetic outcome was also self-judged at the end of the treatment.

CONCLUSIONS: icoone[®] suction therapy provides objective and subjective evidences of cosmetic and microcirculation functional improvement, especially in patients younger than 40 years old.

KEY WORDS: Leg; Microcirculation; Therapy.

The multi-micro stromal stimulation system therapy is an electromedical device with the basic claim is to reactivate the mesenchymal tissue either in surfaceal or deep subcutis but also pre- and postfascial layers by stimulating the elastic fibers and sucking-squeezing the fat cells and the microareolar spaces.¹⁻² The aim is to en-

hance the interstitial tissue compliance to such a biphasic mechanical activation, energetically spreading oxygen and micronutrients through the cell membrane barrier to subcellular organs (e.g. mitochondria and ribosomes) uptake and metabolism.

The multi-micro alvear stimulation is very ef-

fective for remodeling almost every part of the body (face, neck, arms, trunk, legs, etc.), not only for aesthetic purposes,³ but also, and especially for rehabilitative and improving some skin problems, such as hypotonia and relaxation,⁴ dermatofibrosis,⁴ keloids,⁵ hypertrophic scars,⁶ etc. The treatment benefits are not only instant post treatment, but also they last for a certain period, because of the “memory” of elastic, collagenic and reticular fibers conditioned by this peculiar passive physical exercise.

On this basis, we evaluated 25 patients affected by mild lymphedema of calves and legs to outline the potential benefits of *icoone*[®] in short and middle term follow-up upon the following parameters: circulation feedback, edematous contours of the lower leg reshaping and subjective symptomatic benefits.

Materials and methods

Twenty-five women aged between 23 and 75 years old were admitted to the treatment at the Second Opinion Medical Office (Modena, Italy), approached by them in order to steadily improve — swollen legs and calves, and standing discomfort due to impaired microcirculation. This spontaneous and anecdotal study adopted prefixed standardized treatment protocols (and not tailored to individual problems) based on the physical principles of *icoone*[®] function, in order to achieve more reliable statistical data.

Inclusion criteria included the enrollment of healthy, active women, with calves and ankle swollen, due long standing or physical effort; the lymphatic flow impairment had been instrumentally (photoplethysmography) previously between 2 and 20 years before. The patients were submitted to eco-color Doppler to rule out venous impairment or thrombosis. Exclusion criteria were obesity (Body Mass Index [BMI] over 40), diabetes, severe hypertension, kidney insufficiency with lymphedema and severe cardiovascular problems specifically thromboembolism, thrombophlebitis. Any diuretic, cardiocinetic, calcium-antagonist or vasodilating drug plus any compound modifying the coagulation setting was withdrawn at least 4 weeks before admission, enclosing also nutraceuticals

interfering with the vascular wall permeability (e.g. antioxidants, rutosides, ginsengosides, esferidine, anthocyanin resveratrol, etc.).

All the subjects were standardized in terms of dietary and fluid intake, lifestyle (50 minutes' walk/day was mandatorily prescribed) and smoke (smoke was forbidden at least 2 months before).

The trial treatment was performed with *icoone*[®] (i tech-Industries, S. Lazzaro di Savena, Bologna, Italy; Figure 1): a specific robotized device composed of twin microstimulators harboring a system of aspirating channels on their surface, and an intense suction source in the middle. The activation of the procedure involves automatic progression and pressure upon the skin of the microstimulators along a straight line. The caregiver presses adequately upon the handle thus squeezing the skin surface that contemporarily is aspirated and modulated in the middle space of the microstimulators. This allows strong adherence due to the contemporary



Figure 1.—*icoone*[®] robotized device, i tech-Industries.

suction by the incorporated channels. In this way, the fine sub dermal lymphatic network and the subcutaneous one are strongly imprinted by the rhythmic physical antagonizing exercise and intensive enhances the lymph flow to the deep trunks; meanwhile the elastic fibers are stretched triggering a back and forth toning expansion retraction whose effect lasts for some time.

The session lasted 15 minutes each leg: contemporarily the robotwings were moved up and down from the ankles up to the popliteal space and femoral epicondyle areas both sides along three main lines: posterior, lateral and medial. No other traction or actions have been introduced.

The procedure was repeated twice a week for one month and the patient were re-evaluated one month after the end of the treatments cycle (without any maintenance treatment during the last month): no elastic stocking was admitted in the interval, but plain correct feeding, weight loosening and physically active lifestyle monitoring.

The pre and post measures were registered at each session and during the final visit of the follow-up.

Each woman was asked to answer a questionnaire of subjective benefit so if the treatment with the following items:

- legs feeling after the session (A) worsened=1; unchanged=2; lighter legs=3;
- urine output after the session (B) reduced=1; unchanged=2; diuresis induction=3;
- energy after the session (C) reduced=1; unchanged=2; energy and wellbeing=3;
- esthetic outcome after 1 month (D) worsened=1; unchanged=2; aesthetic appearance=3;

Side effects or other untoward mechanisms were regularly signed.

The quality of the skin was evaluated with a non-invasive multi-parametric point of care diagnostic tool (Skin Tester, Selenia Italia, Figure 2), which provides an evaluation of skin parameters, such as dermis embedding, pH, elasticity and sebometry. The working principle of this instrument is based on an ultrasound-emitted beam, which is reflected by the dermal tissues, according to its density and vascular tone. Impedance variations are related to intracellular and interstitial water content and photoplethys-



Figure 2.—Skin tester, Selenia Italia.

mography, a method based on the evaluation of vascular network dynamics. In this study, we have considered the assessment of elasticity and dermis embedding, before the treatment and after 1 month. In this context, Skin Tester was able to detect total, intracellular and extracellular water and water retention in order to evaluate skin dermis embedding. While skin elasticity is related to elastin, collagen and glycosaminoglycan (GAG) content. The parameters evaluation occurs in 30 seconds thanks to a recording of the operative data on a touch screen display. The procedure of skin quality evaluation consisted in the application of a flat transducer over the skin surface, which required a gel film to achieve ultrasound delivery. Finally, analysis results were printed on a ticket including also the references values.⁹

Statistical analysis

Data analysis was performed with GraphPad Prism version 4.0 (GraphPad Software, San Diego, CA, USA) and with R 2.12.2 (R Software; Alcatel-Lucent USA, Inc., Calabasas, CA, USA).

Results

In Table I, data of body parameters analyzed with icoone® treatment: height (cm), weight (kg), BMI, and foot, ankle and leg circumference (cm) before treatment, post treatment (1 month) and at follow-up (1 month) are reported. Table II shows the skin parameters (elasticity and dermis embedding) assessed before treatment and after

TABLE I.—*Body parameters assessed by icoone® treatment (N.=25).*

Body parameters			Before treatment (cm)			After 1 month (cm)			Follow-up (cm)		
Height (cm)	Weight (kg)	BMI	Foot	Ankle	Leg	Foot	Ankle	Leg	Foot	Ankle	Leg
160	65	25.4	30	28.7	46	26	26	43.2	28	25	44
162	70	26.7	28.2	25.6	43.1	25.4	22.3	39.6	26	23.4	38
158	56	22.4	27.6	25.8	41.4	24.2	22.9	37.8	25.4	23.2	38.5
150	59	26.2	25.2	29.8	45.6	22.5	26.4	42.9	23.8	27.2	43.7
161	69	26.6	30.1	29.7	44	26.3	26.2	40	28.2	27	42
168	85	50.6	30.4	27.3	42.8	26	24.2	39.6	28.5	25.7	40
166	70	25.4	27.4	29.6	42.8	24.7	28.4	41	25.2	28.4	41.5
154	59	24.9	29.6	30.2	42.9	28.4	28.5	40	28.8	29.6	41
160	74	28.9	34	32	44	31.8	29	41	32	30	42.7
162	64	24.4	27.3	25.2	43.8	23.6	22.7	40.6	25.2	23.3	41
159	73	28.8	29.5	27.6	42.9	28.5	25.4	40	29	27	41.2
152	66	28.6	26.3	28.4	45	25	28	43.5	26.5	29	43.8
161	65	25.1	27.4	23.9	42.6	24.5	22	40	26.6	23.5	42.8
158	72	28.8	23.8	25.6	39.5	22	25	37	23.9	26	40
166	74	26.9	24.3	25.8	41.6	22	22.6	37.4	23	23.8	39.2
163	60	22.6	29.4	25.2	40.7	27.1	23	37.1	26	24	39.8
168	62	22	39	27	38	36.8	25	36	39	26.8	37.8
172	67	22.6	29	26.4	37.6	27	25.4	37	28.1	25.9	37.2
171	72	24.6	26.4	24.9	42	25.7	24	41.5	27	25	42.4
163	59	22.3	25.3	26.7	36	23.4	25	35	24.2	26	35
153	59	25.2	32	25	40	29.6	23	37	31	24.5	38.7
158	55	22	25	26.5	38.8	23	26	36	24.6	27	39
171	66	22.6	26.4	27.3	35	26	25.8	34	26.8	27	35
158	54	21.6	25.2	29.6	39.4	23.8	26.9	36.7	25	28.4	38
174	66	21.8	27	25	37.8	26	24	35.7	26.7	25.3	37

TABLE II.—*Skin parameters assessed by Skin Tester.*

Before treatment		After 1 month	
Elasticity Ref. values >26	Dermis embedding Ref. values <35	Elasticity Ref. values >26	Dermis embedding Ref. values <35
18	54	21	40
23	38	29	35
15	51	22	45
17	62	19	46
24	40	25	38
22	46	24	41
26	51	28	44
25	37	25	35
20	42	27	36
24	48	26	43
21	39	24	37
23	37	26	35
19	50	25	40
14	37	27	32
29	39	37	33
18	48	24	41
22	39	27	34
16	36	26	33
24	49	27	37
20	42	27	33
16	67	21	49
23	36	28	32
27	35	32	35
22	42	27	39
21	52	29	39

1 month. A score of elasticity (>26) and a score of dermis embedding (<35) are considered as optimal values.

The Anova Test showed a significant reduction of foot, ankle and leg circumferences after 1 month ($P=0.019$; $P=0.001$; $P=0.002$ respectively), but not at the follow-up. A significant correlation was also present between the BMI and

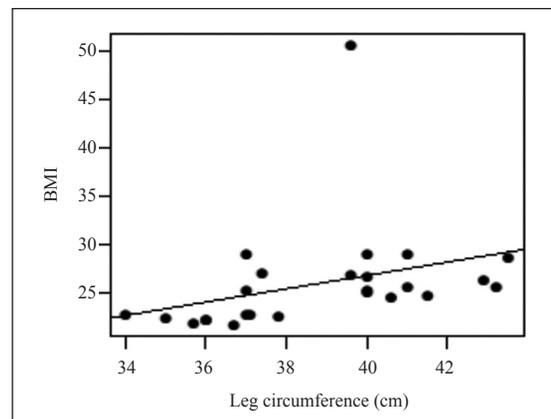


Figure 3.—Significant correlation between BMI and leg circumference before starting the treatment ($P=0.002$).

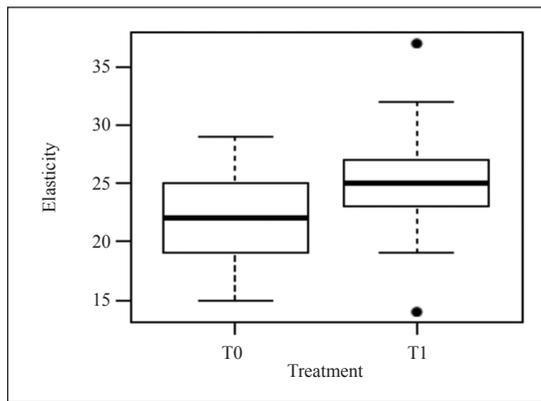


Figure 4.—Significant increase of skin elasticity after 1 month (P=0.01; T0= before treatment; T1= after 1 month).

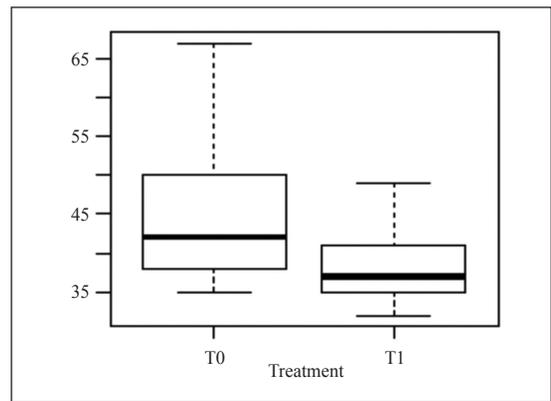


Figure 5.—Significant reduction of skin dermis embedding after 1 month (P=0.001; T0= before treatment; T1= after 1 month).

leg circumference measured before starting the treatment (P=0.002) (Figure 3).

A significant increase of skin elasticity was registered after 1 month (P=0.01) (Figure 4), while skin dermis embedding experienced a significant reduction after 1 month (P=0.001) (Figure 5).

TABLE III.—Results of benefits self-reported questionnaire.

Item A Legs feeling after the session (1-3)	Item B Urine output after the session (1-3)	Item C Energy after the session (1-3)	Item D Esthetic outcome after 1 month (1-3)
3	3	3	3
2	3	3	3
3	3	3	3
2	3	2	2
2	3	2	2
3	3	3	3
3	3	3	3
2	2	3	3
2	2	2	2
3	3	3	3
3	3	3	2
3	2	3	2
3	3	3	3
2	2	3	2
2	2	2	2
1	3	2	2
3	3	3	3
3	2	3	3
3	2	3	3
3	3	3	3
3	3	3	3
3	3	3	3
1	2	2	2
3	3	3	3
1	2	2	2

The benefits self-reported questionnaire (Table III, IV) showed that 60% of patients felt lighter legs after each session, while 28% did not perceive any benefit, and 12% complained some moderate worsening in terms of short-term paresthesia due to edematous thickening and vein dilation in some skin spots of the leg.

As to micturition post-icoone®-administration, 64% of patients after the session increased urine output frequency and volume.

Seventy-two percent of patients declared satisfactory energy and wellbeing enhancement after the treatment and only 28% no change. Finally, at 1 month after the end of the protocol 68% maintained the improved aesthetic appearance, 32% did not observed permanent benefits.

No side effects were reported.

TABLE IV.—Scores frequency of benefits self-reported questionnaire.

Item	Score 1	Score 2	Score 3
Legs feeling (A)			
N.	3	7	15
Frequency	0.12	0.28	0.60
Urine output (B)			
N.	0	9	16
Frequency	0.0	0.36	0.64
Energy (C)			
N.	0	7	18
Frequency	0.0	0.28	0.72
Esthetic outcome (D)			
N.	0	8	17
Frequency	0.0	0.32	0.68



Figure 6.—Legs remodeling, after 1 month. Age of patient >40 years old.

Figure 6, 7 show the legs improvements after 1 month of icoone® treatment. A notable reduction of the circumferences of legs and ankle is observable, particularly in patients younger than 40 years old.

Discussion

Lymphedema of calves, ankles and whole lower legs, can be idiopathic. Alternatively, multifactorial frequency is coupled with heart failure, restrictive cardiomyopathy, nephrotic syndrome, renal failure, and hypoproteinemia.⁶

Diuretics and/or limbs elevation, traditional symptomatic milestones of lymphedema, are often inadequate to remove enough amount of fluid and prevent worsening. Elastic compression stockings are used as well to prevent edema in patients with venous or lymph impairment or even healthy persons.⁷

icoone® device has been proven safe and helpful in counteracting mild calves and ankles edema: in our study after a bi-weekly treatment cycle, the results lasted more than 4 weeks up to two months. After this interval 1-2 sessions/monthly (depending of the severity of the disease) are advisable in order to maintain the advantage and counteract the lymph pooling damage effectively avoiding, dermal thickening, fibrosis and even ulceration, especially when primarily or secondarily the venous system is involved. With periodical icoone® maintenance



Figure 7.—Thighs remodeling, after 1 month. Age of patient: <40 years old.

cycles, results have curative impact; the interval between the treatments is individually tailored and depends on the clinical picture. Obviously, the younger cohort of women under 40 years old and with the lower BMI claims the best outcome, but the overall result from a heterogeneous treated population is quite positive. From the statistical point of view the pre post-treatment leg diameters at three different levels were significantly improved immediately. The significant reduction of foot, ankle and leg circumferences after 1 month, if the treatment is abruptly dropped is not persistent. Water tissue content and skin elasticity measured by the Skin tester confirmed the lymphedema reduction, and instrumental benefit is extended up to 30 days. Satisfaction of the patients was quite high and neither side effects nor treatment drop out happened along the study.

Conclusions

In conclusion, notwithstanding the limited size of our cases cohort and the standardized treatment, there is subjective, and objective evidence that the treatment with icoone® is effective in lower legs health preserving especially if periodically repeated, and if required integrates dynamically the function of elastic stocking support.

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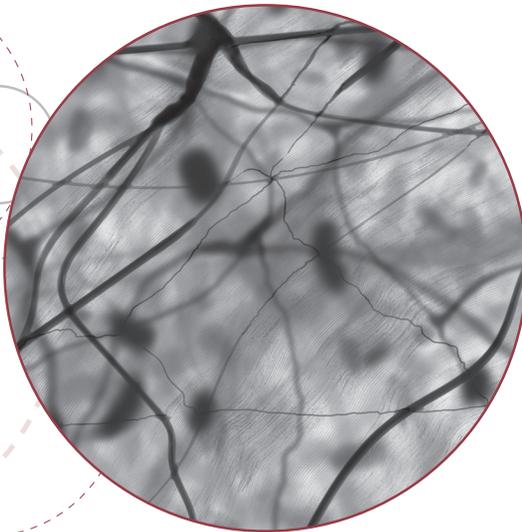
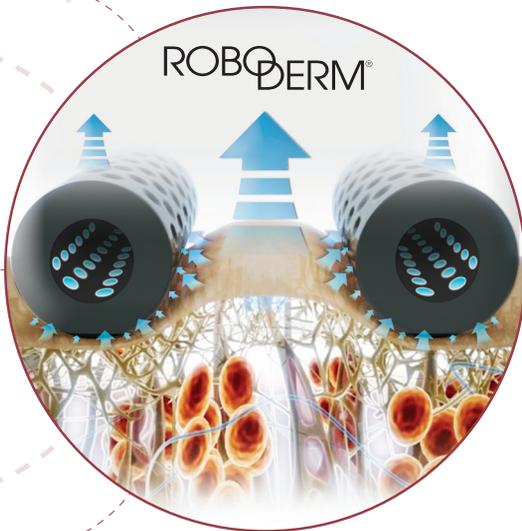
Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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