



PROF. PALMIERI'S STUDY



A new technology for connective tissue microalveolar stimulation: ICOONE®-H

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ICOONE®-H is a newly designed electro-mechanical medical instrument planned to drain the veino-lymphatic cutaneous network acting upon the alveolar interstitial spaces of the connective tissue thus moving effectively the sequestered fluid. The basic action mechanism involves a mechanical friction by rotating and aspirating rollers and an aspiration vacuum chamber in the middle, which softly traps the skin and induces motility of the dermal and subcutaneous vascular channels; three different actions are thus identified: draining and pressing at the two lateral frameworks of the handle, skin stretching and connective fibrils dynamic stimulation in the central part, and reflex neurovascular motility triggered by the back and forth movement of the ICOONE®-H over the anatomical segments to be treated.

Our experimental investigation demonstrates that the effectiveness of ICOONE®-H treatment can be addressed beyond cosmetic and aesthetic medical area, also to specific skin diseases related to abnormal connective tissue reaction like hypertrophic skin keloid and burns.

Also peripheral vascular or edema skin ulcers, lymphatic ectasia are dramatically improved by a cycle of ICOONE®-H treatment.

Even constipation due to hypotonia of the gut can be improved by ICOONE®-H administration probably through mechano-receptor reflexes of the skin.

Received on September 17, 2008.

Accepted for publication on September 25, 2008.

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The safety of the instrument has been definitely confirmed in 100% treated cases with the highest compliance due to the pleasant and relaxing effects of the ICOONE®-H-skin interaction. Conclusively we recommend the use of the instrument either in cosmetic problems or in medical disease trials, when connective tissue as well as microcirculation impairment are involved, and when visceral reactivity has to be elicited by neurosensorial dermal reflexes

Key words: **Surgical instruments - Cellulitis - Massage.**

Introduction

ICOONE®-H medical version technology, called ICOONE®-H, has been introduced to us for the purpose of assessing the instrument's range of physiotherapy performances in the clinical practice

ICOONE®-H is a special rolling and aspirating electronic machine whose handpieces applied over the skin, are: a main RoboSolo with greater contact surface (10 cm × 2 cm × 2 cylinders) and two smaller identical devices for symmetric handling called Robotwins. Each of handpiec contains two rotating cylinders that are perforated uniformly over the entire surface, delimiting an aspiration chamber, through which, and together with the

rollers, fractionated suction of the skin tissue takes place.

Through the supply of a particular conformation of mechanical energy, ICOONE®-H stimulates of the entire skin structure: the epidermis, superficial dermis and deep dermis. Its action is additionally effective on fat and muscular tissue, but its innovative technology, is being addressed to skin elasticity and dystrophic panniculopathy reshaping. The substantial difference between ICOONE®-H and the devices of the previous generation is a clear-cut advance in physiopathology and therapy due to its rationale and ergonomic skin stretching and pressing. The sequential use of fractionated and rhythmic negative pressure on the skin, interfering with the vessels pulsatility of the dermic panniculus, naturally modulates also the fine sympathetic and parasympathetic nerve network, being this reflexology approach, very effective to squeeze mechanically and drain the interstitial tissue lymph, through vasomotor reaction. This strategy fits, not only for cosmetic skin improvement, but also for musculoskeletal and visceral disorders. The hypothesis of ICOONE®-H action mechanism is the production of a mechanical stress of the micro alveolar vacuoles formed in between the collagen fibres of the widespread mesenchymal tissue, providing a specific antigravity counterforce through the rollers holes, whose, high frequency negative pulses (1180 times per dm²). actively modify the steady state of connective tissue

Rationale of the research

The skin function is not just a passive integumental protection of the deep structures, fasciae and muscles, as well as organs and sensory and functional apparatus, by means of a fasciculated and lobular layer of adipose tissue, but it has also organ specificity, with systemic biochemical and neurotransmitters signals. The hydroelectrolitic imbalance of liver, hearth and kidney, for instance, is partially absorbed by the skin, but also neuromuscular diseases degenerative or regenerative reac-

tions as well as inflammation induces skin reaction effect, and can reversibly be modulated by adequate skin treatment.

The basic concept, which underlies all mechanical physiotherapy instruments, delivers rhythmic superficial-to-deep massaging that reproduces the flexibility of the human hand as much as possible inducing an active or passive skin structures stimulation perspective. The human hand, however, lacks a specific function that is more strictly physical: vacuum suction and rhythmic pressure. In fact, the human hand can pinch (pinching), lift and stretch skin, but it does not have this capacity for fractionated pulsatile action. Together with the mechanization of the two twin rollers, this action has a positive effect on the interstitial fluid dynamics. Compared with hand massaging, the rotating movement of the heads on the skin induces an excellent active friction interaction, especially when the rotating movement of the rollers centrifugally clear the gravity-pooled interstitial lymphatic fluid as a result of the vacuum therapy suction.

Based on this complex rationale we conceived a few specific operative protocols for different skin and deeper organs diseases. We also treated adipose tissue nodular cellulitis in the upper thigh and abdominal area, accordingly with a specific protocol, followed up by a specific subjective and objective questionnaire

Materials and methods

Being this instruments CE mark and safety standards conformity provided, the patients were voluntarily enrolled in the study, with prior verbal informed consent. The primary study endpoint was addressed to the SAFETY and EFFECTIVENESS accordingly with the manufacturer claim (this instrument is market available in conformity with cosmetic treatment, rules and no ethical committee had to be required).

Ten cases per group were selected. Exclusion criteria were: haemorrhagic diathesis, an iatrogenically or pathologically induced coat imbalance status (INR above 2.5), severe

cardiac failure with fluid imbalance, kidney insufficiency, and exudative immuno-allergic skin reactions. The following drugs were permitted: antihypertensive (with the exception of diuretics), antibiotics and antidyslipidemics.

Contraceptives, anti obesity pills, flebotrophics beta blocking and topical products such as creams, ointments and liniments, Causing bias in the assessment of ICOONE®-H effectiveness where dropped out at least 4 weeks before treatment start -up.

A specific program suggested by the manufacturer was used in each group of patients on a schedule of, a 10 sessions twice weekly, followed by results evaluation obtained and final judgement

Lymphoedemas vascular problems

Patients selected on the basis of venous lymphatic problems and with skin ulcers or oedema on the lower limbs

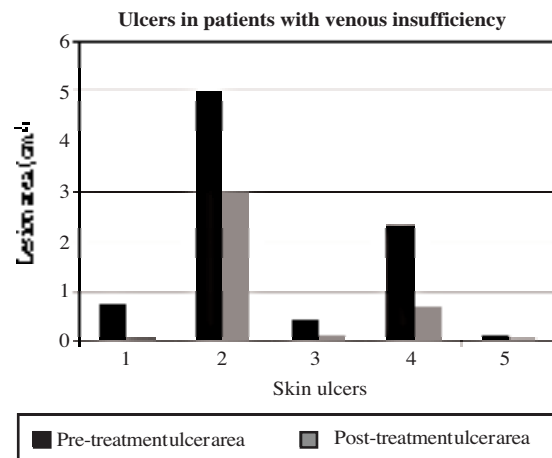


Figure 1.—Progression of ulcerous lesions in patients with venous insufficiency, following treatment with ICOONE®-H.

The protocol required measurement and a functional morphological description of the limbs with the Doppler exam performed during the three preceding months; 20-minute applications of the lower limb ICOONE®-H program, applied longitudinally and in a cir-

TABLE I.—Patients with venous insufficiency and ulcerous lesions, treated with ICOONE.

Patient	Age	Pathology	Pre-treatment lesion (cm)	Post-treatment lesion (cm)	Notes
C. A.	84	Venous-lymphatic insufficiency with trophic skin ulcer on right lower limb	0.8	0.06	Pain: pre: 4, post: 1; ankle stiffness: pre: 4, post: 2; swelling: pre: 5, post: 2; strong acceleration of the levelling off of the ulcerated depression by granulation tissue, reduction in long-standing diameters, lymphoedema reduction; subjective assessment: excellent (5)
G. A.	74	Post-osteomyelitic trophic lesion on right lower limb with severe muscular and cutaneous atrophy of leg and ankle	5	3	Pain: pre: 5, post: 3; ankle stiffness: pre 5, post 3; swelling: pre: 2, post: 1; reduced bleeding and congestion from stasis; subjective assessment: excellent (5)
R. L.	66	Venous ulcer in distal third of tibia treated with zinc stocking	0.48	0.16	Phlogosis: pre: 3, post: 2; malleolar oedema: pre: 20, post: 17; pain: pre: 5, post: 3; subjective assessment: excellent (5)
M. G.	74	Ulcer in lower third of mixed venous-lymphatic aetiology	2.34	0.7	Oedematous skin: pre: 4, post: 2; pain: pre: 5, post 4; malleolar stiffness: pre: 5, post: 3; subjective assessment: excellent (5)
A. M. G.	62	Right epimalleolar ulcer in patient with dyschromic skin and peripheral venous insufficiency	0.12	0.04	Pain: pre: 4, post: 1; stiffness: pre: 4, post: 1; subjective assessment: excellent (5)

TABLE II.—*Patients with venous insufficiency or lymphoedemas with oedemas involving the lower limbs, treated with ICOONE®-H.*

Patient	Age	Pathology	Pre-treatment lesion (cm)	Post-treatment lesion (cm)	Notes
P. E. (1)	39	Venous-lymphatic with phlebo-lymphoedema aggravated by posture	20	18	Heaviness: pre: 5, post: 3; joint stiffness: pre: 5, post: 3; subjective assessment: excellent (5)
P. E. (2)	39	Venous-lymphatic with phlebo-lymphoedema aggravated by posture	16	14	Heaviness: pre: 5, post: 3; joint stiffness: pre: 5, post: 3; subjective assessment: excellent (5)
S. P.	45	Outcome of thrombophlebitis in left lower limb, venous congestion in limb and trophic disorders (dyschromia, keratosis and itching)	19	18	Dyschromia: pre: 5, post: 3; keratosis: pre: 5, post: 2; itching: pre: 4, post: 2; subjective assessment: good (4)
T. C.	68	Venous-lymphatic insufficiency affecting right lower limb previously treated with EVLT unsuccessfully (lympho-edema, pain and functional limitations)	24	21	Dyschromia: pre: 4, post: 3; pain: pre: 5, post: 2; subjective assessment: good (4)
Di C. A.	56	Cardiopathic, previous valvulotomy, with venous insufficiency affecting lower limb more severely	16	14	Dyschromia: pre: 4, post: 2; dyskeratosis: pre: 5, post: 3; pain: pre: 4, post: 2; subjective assessment: good (4)
S. G.	76	Lymphoedema involving lower limbs in patient with polyneuropathy	16	14	Cramps: pre: 5, post: 3; pain: pre: 5, post: 2; subjective assessment: good (4)
F. D.	75	Lymphatic insufficiency involving lower limbs, malleolar oedemas, pain also with tibial periosteal pressure	22	20	Pain: pre: 5, post: 3; pretibial periosteal pain: pre: 5, post: 3; subjective assessment: good (3)
A. M. (1)	84	Lymphatic insufficiency, water retention, oedemas involving lower limbs	23	20	Itching: pre: 5, post: 2; malleolar stiffness: pre: 4, post: 1; impetiginization: pre: 5, post: 2; subjective assessment: excellent (5)
A. M. (2)	84	Lymphatic insufficiency, water retention, oedemas involving lower limbs	21	17	Itching: pre: 5, post: 2; malleolar stiffness: pre: 4, post: 1; impetiginization: pre: 5, post: 2; subjective assessment: excellent (5)
D. T. (1)	55	Hypertension, water retention, lymphoedema	20	17	Itching: pre: 5, post: 3; pain: pre: 3, post: 2; assessment: good (4) limited duration of beneficial effects
D. T. (2)	55	Hypertension, water retention, lymphoedema	19	16	Itching: pre: 5, post: 3; pain: pre: 3, post: 2; assessment: good (4) limited duration of beneficial effects
V. U. (1)	34	Idiopathic lymphoedema	16	14	Stiffness: pre: 5, post: 3; itching: pre: 4, post: 2; subjective assessment: excellent (5)
V. U. (2)	34	Idiopathic lymphoedema	18	14	Stiffness: pre: 5, post: 3; itching: pre: 4, post: 2; subjective assessment: excellent (5)
B. P. (1)	85	Peripheral venous insufficiency and cardiopathy	24	21	Pain: pre: 4, post: 2; stiffness: pre: 4, post: 2; subjective assessment: good (4)
B. P. (2)	85	Peripheral venous insufficiency and cardiopathy	22	19	Pain: pre: 4, post: 2; stiffness: pre: 4, post: 2; subjective assessment: good (4)
T. D. (1)	54	Obesity, hypercapnia, Pick-wickian syndrome, lympho-edema involving lower limbs	29	24	Stiffness: pre: 5, post: 3; itching: pre: 5, post: 3; subjective assessment: good (4)

(To be continued)

TABLE II.—Patients with venous insufficiency or lymphoedemas with oedemas involving the lower limbs, treated with ICOONE®-H. (Continued)

Patient	Age	Pathology	Pre-treatment lesion (cm)	Post-treatment lesion (cm)	Notes
T. D.(2)	54	Obesity, hypercapnia, Pick-wickian syndrome, lympho-edema involving lower limbs	26	22	Stiffness: pre: 5, post: 3; itching: pre: 5, post: 3; subjective assessment: good (4)
B. N.	39	Lymphatic insufficiency involving right lower limb, malleolus and foot due to poorly consolidated multi-fragmentary fracture	19	16	Callosity on plantar surface: pre: 5, post 2; pain: pre: 5, post: 2; subjective assessment: good (4)
S. O. (1)	76	Lymphoedema affecting lower limbs, adiposis hepatica, hypertension	19	16	Itching: pre: 5, post: 3; stiffness: pre: 5, post: 2; subjective assessment: excellent (5)
S. O. (2)	76	Lymphoedema affecting lower limbs, adiposis hepatica, hypertension	20	18	Itching: pre: 5, post: 3; stiffness: pre: 5, post: 2; subjective assessment: excellent (5)
F. M.S.	58	Outcome of left saphenectomy, left malleolar lymphoedema	20	17	Stiffness: pre: 4, post: 2; itching: pre: 4, post: 2; pain: pre: 4, post: 0; subjective assessment: excellent (5)

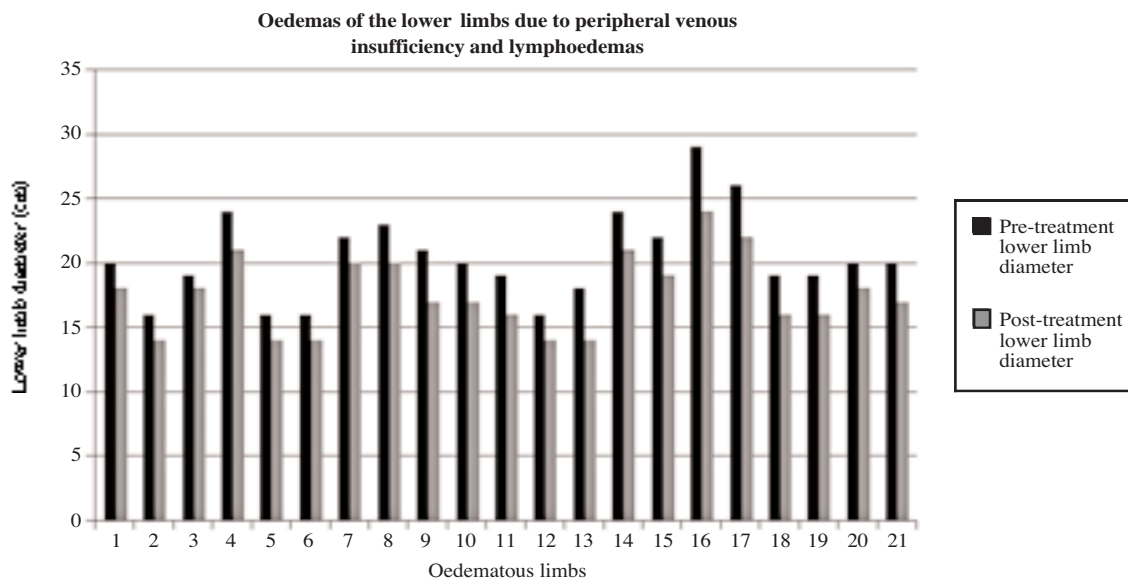


Figure 2.—Progression of the oedemas of the lower limbs in patients with venous insufficiency or lymphoedemas, following treatment with ICOONE®-H.

cular direction over the entire area to be reactivated. The last phase included the questionnaire administered at the end of treatment to obtain a subjective assessment (improved, reduced paraesthesia, less swelling, reduced cyanosis), and comparative pre-/post-treatment measurements of the area, skinfold measurements and an effectiveness assessment.

Lymphoedema treatment: the goal is to drain the swollen tissue and reduce fibrosis

TABLE III.—Program to be set on ICOONE®-H to treat lymphoedemas.

Program
— 2 twins
— 2 Hz - 10 RW - 2 gripp

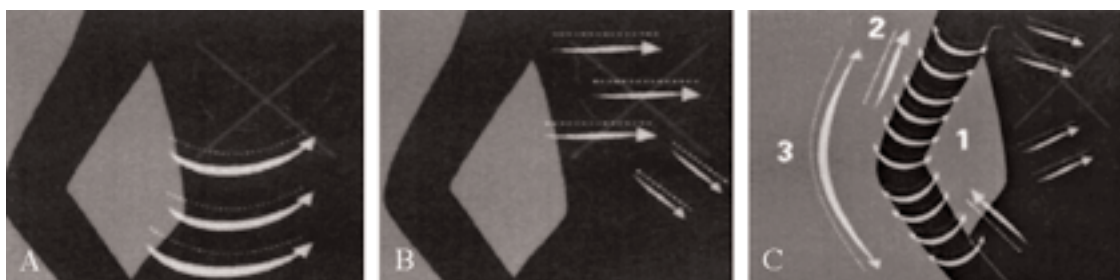


Figure 3.—A-B) Directions of movements to be made with the handpiece to obtain costal drainage. To drain the chest, direct movement on the healthy rib area from the side towards the centre. C) Directions of movements to be made with the handpiece to obtain drainage of the upper limbs. For the arm and forearm: (1) crosswise descending disto-proximal direction; (2) longitudinal ascending disto-proximal direction. From hand to shoulder: (3) longitudinal ascending direction.

Treatment of venous insufficiency: the goal is to stimulate and drain the tissue where veins are inefficient

TABLE IV.—Program to be set on ICOONE®-H to treat oedemas caused by venous insufficiency.

Program
— twins
— 11 Hz - 10 RW - 2 gripp

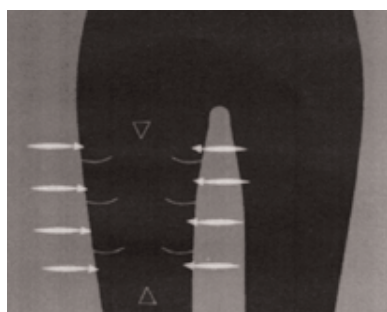


Figure 4.—Directions of movements to be made with the instrument to obtain drainage of the lower limbs. Move handpiece crosswise along the inner and outer thigh area.

Constipation

The end point of gut motility enhancement was tested on a group of idiopathic constipation affected patients, without obstructive history, haemorrhoids, descending perineum syndrome, anal fissures and other previously detected neuromuscular lesions affecting the smooth muscle. Most of the subjects were females, between 20 and 55 years old, with a medical history that

included long standing constipation (bowel movements at intervals of 5-7 days, absence of spontaneous movements, utilization of laxatives, suppositories or micro enemas, used in the recent past – within the last 6 months – contrast enemas or ileal transit, defecography, rectoscopy with anal manometry all proving to be within normal ranges). Patients dropped out laxatives, cholagogues and prokinetic digestive enzymes and a standardized fibre intake was fixed in terms of fruits and vegetables, in addition to an adequate and well balanced proteins, fats and carbohydrates diet.

The treatment started in the epigastric and duodenal region (10 minutes) to stimulate and generate the gastro-duodenocolic reflex and then (10 minutes) along the colon in a caudal-cranial direction, starting from the right iliac fossa lodging at the cecum position, up to the transverse colon and the sigmoid rectum.

The number of weekly spontaneous bowel movements, was registered enclosing the evacuation effort and the amount and quality of stool.

The results were defined as excellent (3) if spontaneous bowel movements were obtained three times per week, good (2) if movements occurred twice weekly, fair (1) if the result consist in spontaneous bowel movement that proved to be easier, and poor (0) if bowel movement occurred once a week with some improvement compared to the previous situation.

The patients complied very positively with the treatment starting from the third session,

*Selected patients with constipation*TABLE V.—*Patients with constipation, treated with ICOONE.*

Patient	Age	Pathology	Pre-treatment lesion (cm)	Post-treatment lesion (cm)	Notes
N.	29	Persistent constipation in patient with previous hemicolectomy	0.5	3	Subjective assessment: excellent (3)
F. G.	62	Idiopathic constipation	0.5	2	Subjective assessment: excellent (3)
Z. G.	59	Post-menopausal constipation	0.5	2	Subjective assessment: good (2)
M. M.	72	Recent onset of constipation in patient with dolichomegacolon	0.5	1	Subjective assessment: fair (1)
M. E.	30	Atonic constipation in polyuric patient	0.5	2.5	Subjective assessment: good (2)
T. G.	62	Constipation in subject with diabetic neuropathy	0.5	1	Subjective assessment: fair (1)
D. C.	60	Constipation due to reduced physical activity	0.5	3	Subjective assessment: good (2)
C. E.	56	Constipation in hypothyroid patient undergoing opotherapy	0.5	2	Subjective assessment: excellent (3)
Z. V.	62	Constipation in subject with recent hysterectomy	0.5	3	Assessment: good (2 also as symptomatic of the abdomen operated on)
C. V.	84	Constipation in asthmatic subject undergoing steroid treatment	0.5	3	Beneficial to skin and deep muscles (greater tone and strengthened prelum abdominale); subjective assessment: good (2)

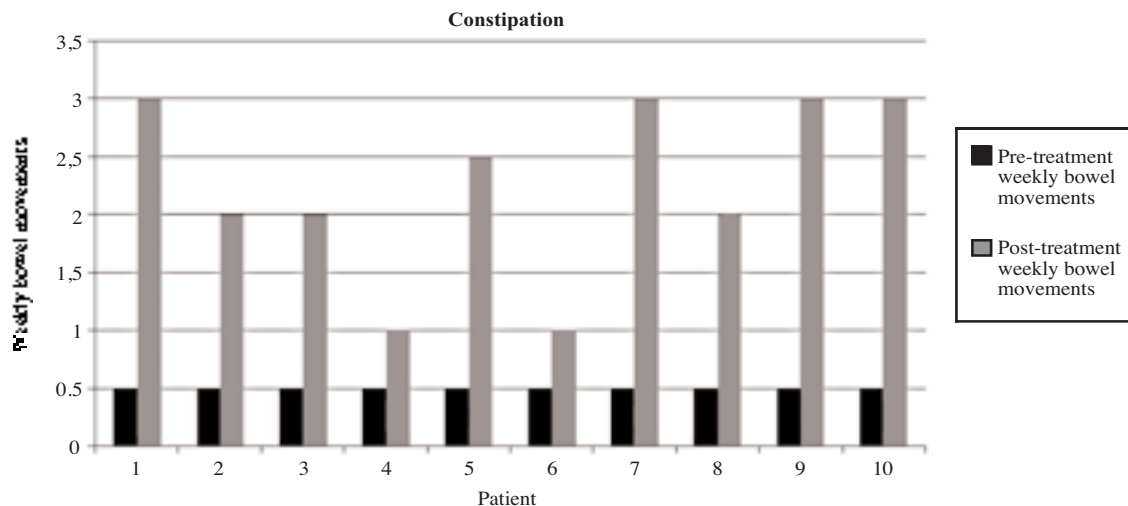


Figure 5.—The course of constipation in patients treated with ICOONE®-H.

and referred less abdominal bloating, greater muscle tone of the ventral abdominal wall, and an increased number of post-prandial borborygms. Fecal output was recovered on each other day in two patients, every 3 days

in 4, every 4 days in 2 and 2 patients showed no changes.

Constipation treatment endpoints: improvement of intestinal transit, diaphragm relaxation and visceral mobilization.

TABLE VI.—Program to be set on ICOONE®-H to treat constipation.

Program
— Twins
— 9 Hz - 9 RW - 3 gripp



Figure 6.—Direction of movements to be made with the handpiece to obtain abdominal drainage and treat constipation. Slow, soft pumping; movement to the left and right of the navel; perform a W-shaped movement over the stomach.

Retracting scars and burns

2nd and 3rd degree burns and keloids forming hypertrophic scars were treated in a 10 Patients group. The evaluation parameters were selected with itching and burning sensations relating to the hypertrophic scars and stiffness in flexion/extension of limbs or extremities before and after the treatment cycle on the retracting scar skin area (the parameters regarding increased joint mobility were measured with a specific goniometer before and after treatment).

Patients filled a pre-/post- questionnaire on symptoms, variations and were then evaluated by a single physician in terms of consistency with the objective evaluation.

Patients selected with retracting scars

TABLE VII.—Patients with scars treated with ICOONE.

Patient	Age	Pathology	Pre-treatment lesion (cm)	Post-treatment lesion (cm)	Notes
L. N.	66	Hypertrophic scar from complicated sternotomy incision	5	3	Pain: pre: 3, post: 1; itching: pre: 5, post: 2; subjective assessment: excellent (5)
G. F.	58	Hypertrophic scar, right subcostalis, from wound infection	5	3	Itching: pre: 5, post: 3; pain: pre: 2, post: 0; subjective assessment: excellent (5)
F. L.	45	Outcome of amputation of foot and retracting wound on dorsum and at ankle with oedema and symptoms	6	3	Subjective assessment: excellent (5)
B. L.	40	Hypertrophic wound on left foot from multi-fragmentary fracture	5	3	Subjective assessment: excellent (5)
M. A.	52	Right retroauricular wound from mastoid cholesteatoma with pains, stiffness and itching	5	2	Subjective assessment: excellent (5)
M. ML.	62	Retracting scar from thyroidectomy with retraction and functional limitation of the neck	5	3	Retraction: pre: 5, post: 3; hypomotility of the neck: pre: 5, post: 3; subjective evaluation: excellent (4)
I.	35	Wound from cut on face, suborbital with scarring retraction and lagophthalmos	4	2	Subjective assessment: good (4)
F. E.	43	Outcome of blepharoplasty with irregular resection of lower eyelid skin	5	2	Subjective assessment: good (4)

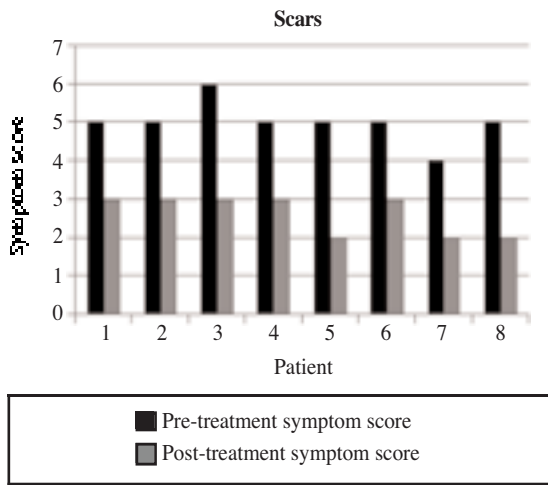


Figure 7.—A) Regression of scar symptoms in patients treated with ICOONE®-H.

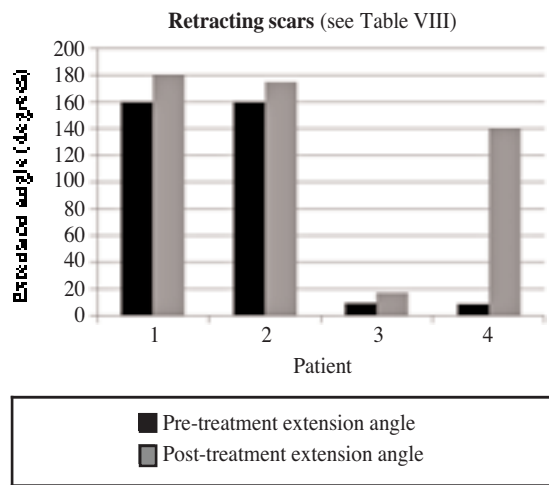


Figure 8. — Recovery of flexion capacity in patients with retracting scars, treated with ICOONE®-H.

TABLE VIII.—Patients with scars and reduced flexion, treated with ICOONE.

Patient	Age	Pathology	Pre-treatment lesion (cm)	Post-treatment lesion (cm)	Notes
B. S.	64	Retracting scar from hip prosthesis (difficulty extending right lower limb)	160	180	Subjective assessment: good (4)
R. P.	39	Scar resulting from burn on right knee, with severe retraction and difficulty extending	160	175	Subjective assessment: good (4)
M. G.	39	Ankle injury and difficulty with flexion-extension of foot	10	18	Subjective assessment: excellent (5)
C. C.	42	Burn on right index finger with ankylosis of the third phalanx upon flexion with difficulty extending it	9	140	Subjective assessment: good (4)

TABLE IX.—Program to be set on ICOONE®-H to treat retracting scars.

Program
Phase 1
— Twin - Skin repair
— 9 Hz - 6 RW - 3 gripp
Phase 2
— Solo - Novaskin
— 7 Hz - 5 RW

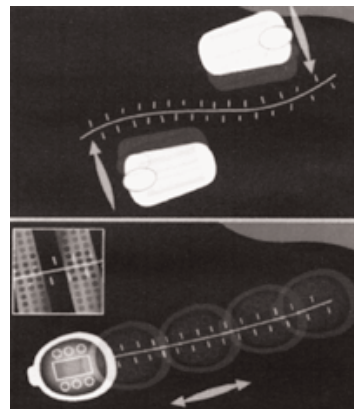


Figure 9. Direction of movements to be made with the handpiece to achieve scar improvement. Pass the instrument alongside the scar and from both sides; pass the instrument over the scar.

TABLE X.—Program to be set on ICOONE®-H for burn treatment.

Program
— Twins
— 9 Hz - 6 RW - 2 gripp

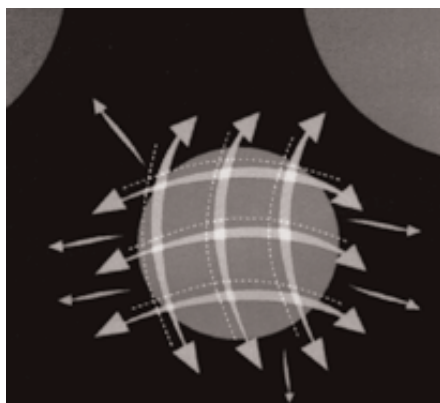


Figure 10. — Direction of movements to be made with the handpiece to soothe, reduce fibrosis and mobilize the burns. To soothe pain, delicately pass over the area following the course of a hypothetical grid; to reduce fibrosis, rapidly pass over the area and lift (plicating) following the course of a hypothetical grid; mobilize adherence of tissue by moving from the inner to the outer section of the scar.

Cellulitis

The cellulitis ICOONE®-H treatment protocol included the selection of 20 female patients, ranging in age from 16 to 58 years. They were generally overweight and with second degree obesity (35), BMI between 25 and 35. standard functional diet with caloric restriction and physical activity, were not required, in order to evaluate the ability of the ICOONE®-H to reduce the circumference of the torso at the anterior superior iliac spine and the thighs, using the contra lateral thigh as control with a simple 15-minute manual massage with Somatoline.

The results were subdivided into a subjective compliance assessment of the following parameters (score range: 0 to 5), pain, orange-peel effect, softness and skin elasticity before and after treatment. Circumference measurements were, in turn, re-evaluated on the basis of putative simultaneous weight loss; in case of weight loss, the effects would evidently be greater, as supported by systemic reshaping and confirmed by local impedance test.

Selected patients with cellulitis and treated with ICOONE®-H

TABLE XI. — Patients with cellulitis, treated with ICOONE.

Patients (ICOONE)	Age	Localization of cellulite	Pre-treatment circumference (cm)	Post-treatment circumference (cm)	Difference in circumference (cm)
T. E.	35	Thighs	60	56	4
V. F.	58	Abdomen, pelvis	88	84	4
G. E.	50	Thighs	59	54	5
A. A.	56	Buttocks	100	96	4
B. C.	65	Abdomen, pelvis	81	76	5
D. A.	58	Thighs	63	60	3
C. S.	56	Abdomen, pelvis	79	74	5
M. R.	42	Abdomen, pelvis	76	72	4
V. E.	52	Abdomen, pelvis	83	80	3
R. L.	56	Abdomen, pelvis	89	84	5
S. M.	45	Abdomen, pelvis	95	92	3
A. A.	40	Abdomen, pelvis	87	84	3
M. M.	42	Abdomen, pelvis	83	80	3
C. E.	64	Abdomen, pelvis	84	81	3
C. R.	66	Abdomen, pelvis	75	70	5
S. G.	62	Thighs	56	53	3
A. R.	46	Thighs	59	55	4
V. L.	50	Abdomen, pelvis	80	78	2
C. V.	49	Thighs	57	55	2
G. A.	42	Thighs	58	54	4

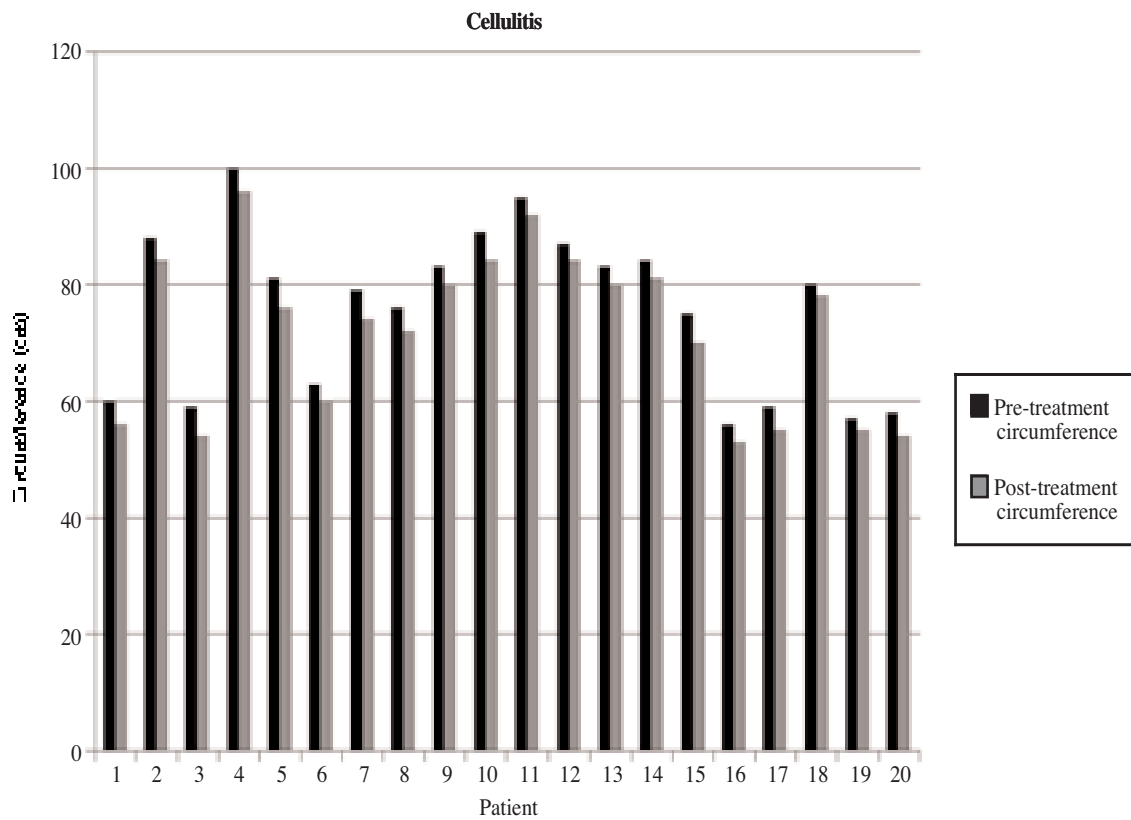


Figure 11. — Reduction of cellulitis following treatment with ICOONE®-H.

Selected patients with cellulitis and treated with somatoline (control)

TABLE XII.
Program to be set on ICOONE®-H for cellulitis treatment.

Program
— 2 twins
— 12 Hz - 10 RW - 2 gripp
— Robosolo after 6 months



Figure 12. — Direction of movements to be made with the instrument for cellulitis treatment. Crosswise and longitudinal movements.

TABLE XIII. — *Patients with cellulitis, treated with Somatoline.*

Patients (Somatoline)	Age	Localization of cellulite	Pre-treatment circumference (cm)	Post-treatment circumference (cm)	Difference in circumference (cm)
C. P.	41	Thighs	61	60	1
D. F.	48	Abdomen, pelvis	78	76	2
M. L.	50	Thighs	68	68	0
P. A.	45	Thighs	59	58	1
L. N.	62	Abdomen, pelvis	84	83	1
R. T.	59	Buttocks	99	98	1
D. G.	51	Abdomen, pelvis	102	100	2
S. Q.	56	Thighs	63	62	1
C. Z.	39	Abdomen, pelvis	89	89	0
F. L.	47	Buttocks	98	97	1
G. V.	50	Abdomen pelvis	81	80	1
E. I.	47	Thighs	68	67	1
T. R.	58	Thighs	65	64	1
O. F.	48	Abdomen, pelvis	90	89	1
S. P.	46	Abdomen, pelvis	86	86	0
I. M.	52	Abdomen, pelvis	100	98	2
N. G.	57	Buttocks	104	103	1
F. R.	48	Abdomen, pelvis	96	95	1
D. O.	46	Thighs	62	61	1
S. C.	50	Thighs	70	69	1

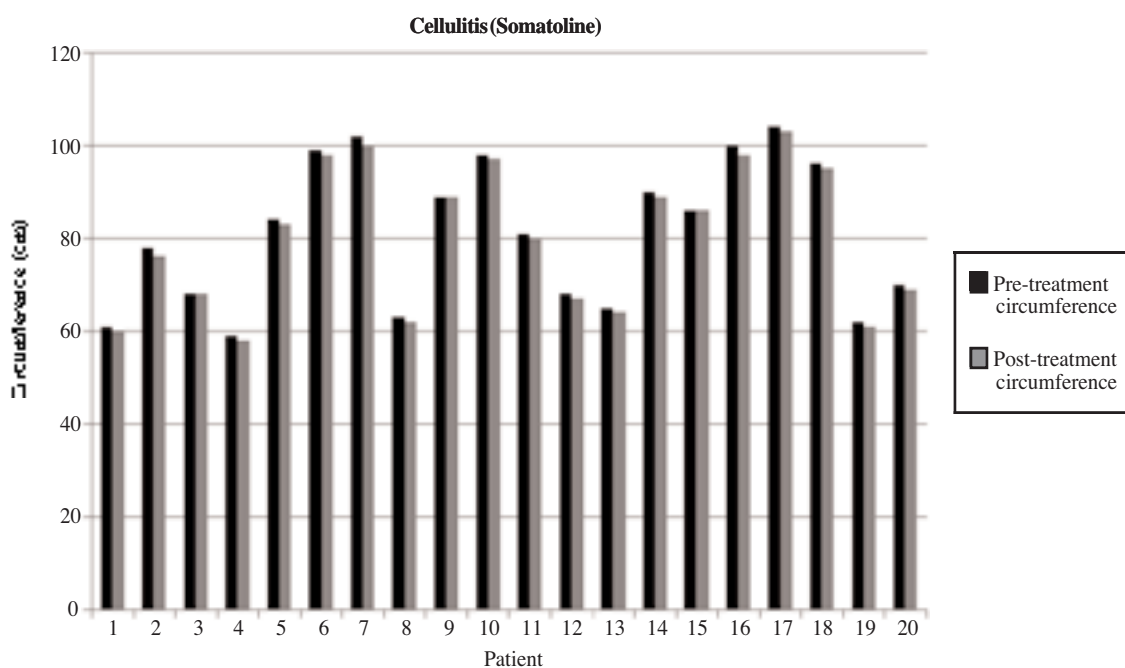


Figure 13. — Reduction of cellulitis following treatment with Somatoline.

Statistical validation of the effectiveness of ICOONE®-H treatment of cellulite

In order to evaluate the statistical significance of the effectiveness of ICOONE®-H treatment of cellulite, administration of Somatoline was introduced as a match control and a statistical analysis of variance (one-way ANOVA) was performed. The comparison circumference differences in the two cohorts showed a clear-cut difference between these treatments: ICOONE®-H proved to reduce the circumferences of every treated area more effectively than Somatoline. The analysis of variance confirmed a statistically significant difference in the effectiveness of the two methods (p-value <0.05; F calculated > F crit), with better performance of ICOONE®-H in the treatment of cellulite.

Results

The results of this preliminary study, on a simple open model basis, proved the effectiveness of ICOONE®-H in each one of the treated diseases. The instrument action mechanism is based on hemodynamic flows and neurofibrillary reflexes of the skin receptors, the mobilization and activation of enzymes and leukocytes to reshape the scar tissue, (including older scars, supplying functional hydration, but also acting probably upon complex and deep neurovascular circuits. The flexible modulation of the skin triggers extraordinary changes affecting the deformability, resiliency and elasticity of the soft tissues especially when the latter have lost their compliance due to dystrophy or degeneration induced by pre-existing pathologies.

Discussion

The results of this study include relevant clinical issues (altered scarring, constipation, phlebo-lymphoedema, etc.), along with other targets related to cosmetic medicine, such as skin pathology, cellulites, etc.

The positive results achieved with ICOONE®-H are emphasized by the exclusion of many

bias due to procedure-related subjective factors: first of all, the operator manual skill is completely ruled out, allowing the performance of well defined comparable protocols and multicenter experimental investigations. In fact, the operator's hand only has to follow up the instrument as it moves over the skin, with no need to perform any reinforcing or supporting manoeuvre at all. Thus the subjective bias of the operator's manual ability is cut off and all the results are related to the patient biological reactivity.

The peculiar ICOONE's property to actively suck the skin by means of the rotating micro-cavity rollers and in the central chamber (see diagram) is critical in terms of effectiveness. The complex suction-pressing activity not enclosed in the previous technologies, is qualitatively remarkable. In fact, the aspirating effect of the handpiece modulates traction on the elastic-collagen matrix of the dermis and the subcutaneous tissue, in a much more gradual, broader and prolonged manner. This definitely increases lymphatic and micro-circulation flow efficacy along the work axis of ICOONE. For this reason the ICOONE®-H massage is very pleasant and restores elasticity and tone of the skin through

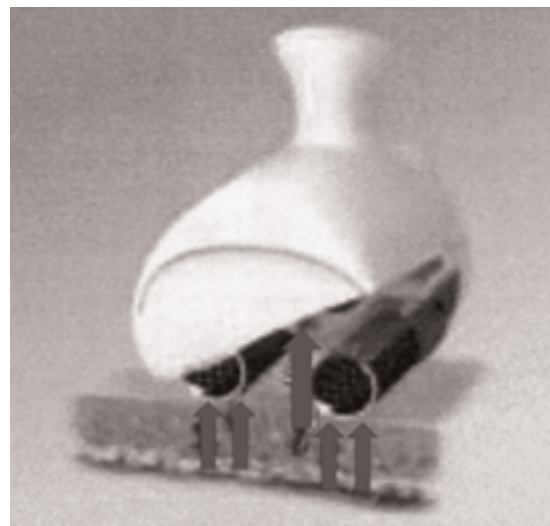


Figure 14. — Diagram of the holes of aspiration in the ICOONE. The instrument performs its aspiration function through the micro-openings on the rotating rollers and through the central chamber inside the mobile head.

the rhythmic mechanical suction and squeezing with definite benefit on macro and micro-circulation.

Another therapeutic goal worth of mention as anedoctical report is the effectiveness of ICOONE®-H in the treatment of lumbar sciatica, epicondylitis, peri-arthritis of the shoulder ("frozen shoulder"), etc. In all these cases, the massage with ICOONE®-H causes a moderate increase. This means that the micro-cavity aspiration stimulates also the sub-epidermic nociceptors, with pain perception. However, within hours after treatment, this is followed by considerable relief and relaxation of the painful area that has been treated, giving longstanding anti-phlogistic effects.

In any case, it is proved that ICOONE®-H induced stretching and elastic response of the hypertrophic scar connective tissue thus reshaping it. This is observed also in fibro-lipo cellulitic tissue, and ICOONE®-H is the ideal instrument for the reshaping of areas that have recently undergone liposuction, with excellent re-distribution of collagen bundles in a more regular network arrangement

Conclusions

Our conclusions support definitely the use of this instrument in cosmetological medical practice, especially in the lower limb management, the burns or surgical scars, the loss of muscle tone in the abdominal and dorsal area with functional impairment for the body and skin. The use of ICOONE®-H proved to be effective not only in the treatment of cellulitis, but also of several dermopathologic syndromes, in a totally safe way, and this

support the hypothesis if different action mechanisms not merely related to mechanical stress to skin and subcutaneous tissues, but on more subtle interactions with chemical mediators, motility, cellular functions, and blood compartment between vessel lumen and interstitial tissue.

Although this study was based on a simple and open schedule due to the difficulty to recruit comparable homogenous the patients' level of satisfaction yielded a very high score, even in the case of inconclusive clinical results (as lymphoedemas). ICOONE's revitalizing mechanism is subjectively pleasantly perceived as something changing in the skin and beneath it. This change has a positive impact on the life quality. However, the objective results achieved with this technology rule out the placebo effect of ICOONE®-H and more complex trials in the future will identify additional niches for effective ICOONE®-H therapy.

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