

Retrospective study

Compressive microvibration with “Endosphères Therapy”

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Between 2000 and 2007, a lot of innovative ideas were presented to the medical world about the treatment of cellulitis and unesthetic lipoedema; very interesting was a new non-invasive methodology that used a revolutionary strategy to create, through the action of 55 soft silicone spheres rotating inside a cylindrically shaped apparatus, different stimulations and vibrations into the tissues aimed at vascularizing, draining, analgesic and restructuring responses. First clinical observations and scientific studies, followed by Professor Raoul Saggini, director of the Postgraduate School of Physical Medicine and Rehabilitation at the “G. D’Annunzio University” of Chieti, and by Professor Pier Antonio Bacci, Professor in Phlebology and Aesthetic Surgery at the University of Siena, highlighted new mechanisms that could be useful in the field of aesthetic medicine, phlebolympology, thermalism, physical medicine and sports medicine. In October 2008, the first scientific rationale was filed with the Official Association of Doctors and Surgeons of Arezzo. The present writing aims to retrace the scientific basis that led to the realization of the new method and the conclusions of that scientific rationale, reviewing it in the light of twenty years of experience with current knowledge.

At the beginning of the new century, many projects and scientific innovations were born to respond to specific requests from the medical world for the treatment of cellulite, lipodystrophy, lipoedema and lipolympheidema; amongst these, a new concept of non-invasive treatment that required seven years of research and experience was created.

This revolutionary strategy was based on the new concept of "compressive microvibration", which used "soft silicone rotating spheres" capable of delivering vibrations into the tissues to provoke targeted stimulations for specific cellular reactions. The first clinical observations were followed between 2000 and 2007 by Professor Raoul Saggini, director of the Postgraduate School of Physical Medicine and Rehabilitation at “G. D’Annunzio University” of Chieti and the Centre for Phlebology and Aesthetic Pathologies of Arezzo, directed by Professor Pier Antonio Bacci,

Professor in Phlebology and Aesthetic Surgery at the University of Siena.

These observations made it possible to identify new interesting mechanisms of action that were also evaluated in clinical practice in various medical centres in the field of aesthetic medicine, phlebolympology, thermalism, physical medicine and sports medicine.

In 2008, the new non-invasive methodology "Endosphères Therapy" was presented to the medical press and scientific world for the first time. This new methodology used a revolutionary strategy of "Compressive Microvibration" to create stimulations and vibrations through the action of 55 soft silicone spheres rotating inside a cylindrically shaped apparatus, aimed at vascularizing, draining, analgesic and restructuring responses.

In October 2008, the first scientific rationale was filed with the Official Association of Doctors and Surgeons of Arezzo. The present writing aims to

retrace the scientific basis that led to the realization of the new method and the conclusions of that scientific rationale, reviewing it in the light of

twenty years of experience with current knowledge.

Materials and methods

Various vascular physiotherapy or rehabilitation techniques are based on the aspiration of the skin by vacuum and lateral traction of the tissues to "stretch" the connective fibres and reduce fibrosis (1-2).

The new strategy overturned this concept of "Aspiration-Traction" for a new idea of "Compression-Microvibration" capable of causing

an "Elastic Response" that would allow exploiting the "Compressive Microvibration" transmitted to the tissues for different functional responses, one of the novelties was in the handpiece that housed an operating cylinder in which 55 rotating spheres of soft silicone were installed, which formed the "Endosphères Therapy" (Fig. 1).



Fig. 1. The 55 rotating spheres of soft silicone housed in the operating handpiece of *Endosphères Therapy* (Courtesy FenixGroup).

The variation of the rotation speed of the spheres determines the frequency of the vibrations.

The frequencies can vary from 40 to 355 Hz. At the same time, the direction of rotation of the spheres and the pressure exerted by the handpiece on the tissues causes a "micro-compression", which, associated with the micro-vibrations

induced by the spheres, drives a continuous pulsed and rhythmic action that produces a positive/negative "pump" effect. The right combination of forces ultimately determines the intensity of the treatment, thus adapting it to the patient's clinical conditions (Fig. 2).

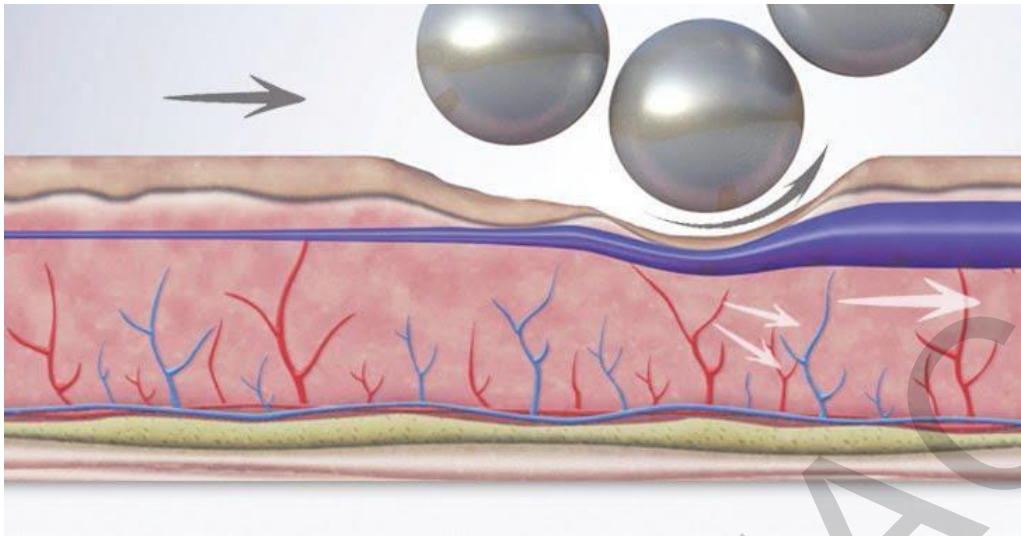


Fig. 2. *The rotation speed of the 55 rotating balls determines the working frequency.*

Among the most significant effects that can be ascribed to the “Endospheres Therapy” treatment are as follows:

- a) Tissue compaction obtained as a result of the disintegration of the adipose compartments
- b) A significant lymphatic drainage action
- c) A significant increase in tissue vascularization and skin temperature
- d) A reduction of inflammatory processes is demonstrated by reducing the "pain" symptom.

In the University of Chieti studies, the method has also shown interesting results in treating the main muscle groups with a sedative action on the hyperexcitability of the nerves, both motor and sensory.

As stated by Prof. Bellomo of the University of Chieti: "Endospheres therapy acts on the muscle by producing a continuous and prolonged tensile

action that arranges the fibres in series and determines an elongation of the connective tissue, thus making it more elastic and more ready to reduce muscle contracture” (3).

The use of the method in sports medicine and trauma rehabilitation (low back pain, neck pain, muscle fatigue, foot pain) was derived from this. At the same time, other experiences and studies carried out in different structures between 2006 and 2008 have demonstrated the particular and innovative features of the "Endosphères®" system concerning the effectiveness of "compressive microvibration" in phlebolymphatic pathologies with swollen legs (acute and chronic lymphedema), in tissue sagging and in the various forms of cellullitic panniculitis (4).

Action on the vascular system

The particular “honeycomb” arrangement of the rotating spheres in the cylinder is in synergy with

the micro compression exerted on the tissues with pressures that stimulate the various receptor

corpuscles (mechanoreceptors, nociceptors, thermoreceptors, trigger points and TuiNa) that give life to the different vascular and metabolic actions (5-7).

The elastic response of the tissues to the stimulation of the microspheres creates micro-lifts and positive/negative tissue translations that ultimately generate “vascular gymnastics” that favours the microcirculatory improvement (Fig. 3).

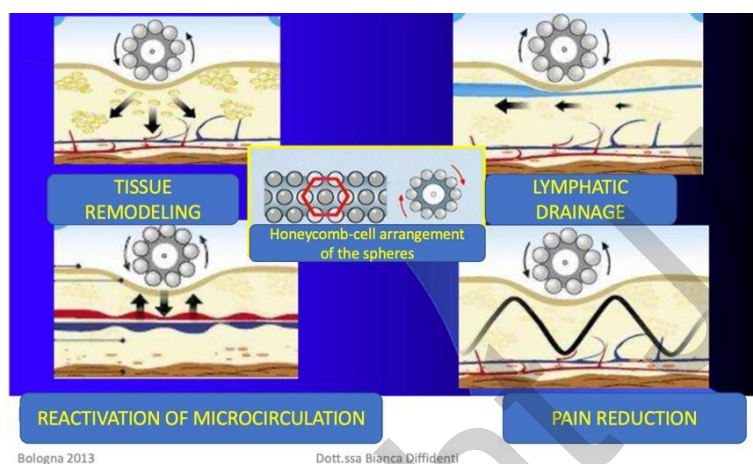


Fig. 3. Honeycomb arrangement of the rotating spheres that generate micro-lifts and micro-vibrations (Courtesy B. Diffidenti).

The "Endosphères" method allows counterbalancing the venous vessels' hydrostatic pressure by reversing, as in the Vodder Lymphatic Drainage, the intimate metabolic and hemodynamic exchange mechanism with inversion of the flow.

Studies show that Endosphères causes an increase in skin temperature with a significant effect on vascular hemodynamics which can be particularly

useful in sports medicine and in forms of advanced cellulite with fibrous orange peel which represent the most widespread and least tolerated imperfection for women.

The studies carried out in the Digital Telethermography Centre of the Institute for Advanced Biomedical Technologies - I.T.A.B. of the University of Chieti, in fact, demonstrated this vascular and thermal activity on the tissues (8).



Fig. 4. Post-treatment thermal increase evaluated thermographically (Courtesy Fenix).

This effect of the thermal increase, concluded Dr Merla, head of the Digital Thermography of the ITAB Institute, can certainly be the result of "the increased perfusion and oxygenation of the skin, the increased metabolism of the tissues, the disintegration of adipose aggregates as well as the activation of anti-inflammatory repair processes of tissue alterations present" (Fig. 4).

These conclusions agreed with the observations made in the same years in the Centre for Aesthetic Pathologies of Arezzo, where the same thermal

increase was highlighted due to improved tissue vascularization.

In the sixteen subjects studied, an average increase of 3.14% in fibroedema of the thigh was seen, while in the targeted treatments on the trochanteric region (culottes de cheval) there was an average increase of 7.14%, highly justifiable for the presence of steatomeric and superficial adipose tissue, as well as a bone base that enhanced the vascular treatment (9) (Fig. 5,6).

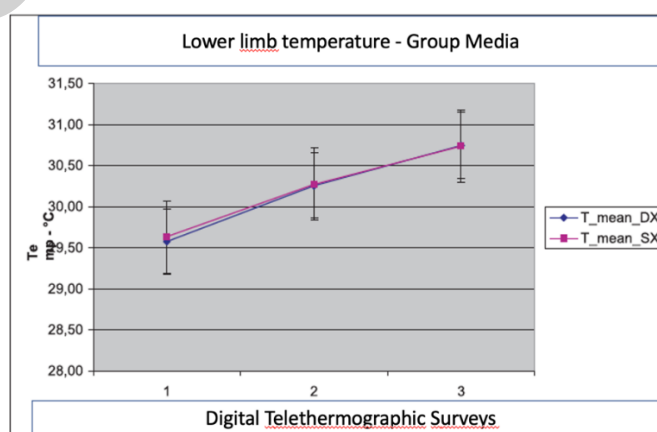


Fig. 5. Average post-treatment thermal increase evaluated with thermolaser (Courtesy Prof. Bacci).

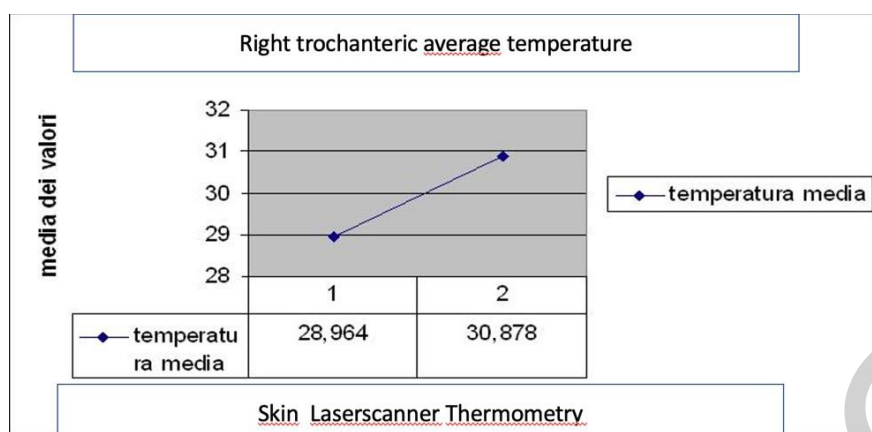


Fig. 6. Average post-treatment heat increase assessed in the trochanteric regions with a thermolaser (Courtesy Prof. Bacci).

The vascularizing effect obtained always favours a better lymphatic drainage activity which reduces stasis and brings a sense of lightness and well-

being to the legs which ultimately improves the patient's quality of life.

Action on the lymphatic system and the interstitial matrix

Over time, the stasis of toxic substances alters the state of the interstitial matrix and the very structure of the tissues, favouring the evolution towards fibrosis and, particularly in women, in the typical evolutionary fibroedema.

The persistence of stasis and edema is always associated with an increase in free radicals and tissue acidity with consequent alterations of the metalloproteases and evolution towards fibrosis, with evidence of tissue and myofascial tenderness caused by the toxic substances present, the lower oxygenation and by reduced purification.

All this favours the activation of the processes that lead to the retraction of connective fibres and the evolution of cellulite, called E.F.S.P (EdematoFibroSclerotic Panniculopathy) or F.E.F (Female Evolutive Fibroedema) (10, 11).

The so-called lymphedema is not always caused by alteration and/or obstruction of the lymphatic vessels with the formation of edema and an increase in interstitial fluids, but can also be a consequence of the alteration of the functional activities of that "interstitial matrix" which regulates the balance of reactions vitality of cells and tissues, together with the control of the "clarity" of that "internal sea" which, when altered, tends to assume a denser and more fibrous state.

The fundamental characteristic of the matrix and the connective tissue is "plasticity", that is the ability to adapt to various situations by changing the structure of the tissues and the action of the cells.

When this characteristic is altered, the tissues activate the aging processes that lead towards the

formation of an evolutionary fibroedema clearly visible in the subcutaneous and in the female skin with orange-peel effect (12, 13).

The typicality of the rotation of the soft silicone spheres that characterize the "Endosphères" method determines a pulsed and rhythmic action carried out by the cylinder guided by the operator's hand, depending on the direction of rotation of the spheres themselves.

The propulsive thrust that acts on the lymphatic system eliminates excess fluids and reduces lymphatic stasis allowing new metabolic activities to the extracellular matrix, which benefits from better vascularization.

The lymphatic drainage action is obtained thanks to the activation of the lymphatic pumps induced by microvibrations and microcompressions, without the possibility of damage to the tissues.

This edema reduction effect was one of the most interesting results recorded in 2007/2008 in various Italian medical centres during daily practice.

The lymphatic drainage and metabolic effect detected agreed with the clinical observations made on the patients monitored in the Centre of Documentation in Aesthetic Pathologies of Arezzo (14, 15).

It is interesting to note how the results of the treatment continue over time, improving the effect from 30 to 60 days, both in the reduction of heaviness and in the reduction of edema and cellulite.

In the multicentric there is no weight reduction because the treatments were done only on the lower limbs and not on the visceral fat of the abdomen.

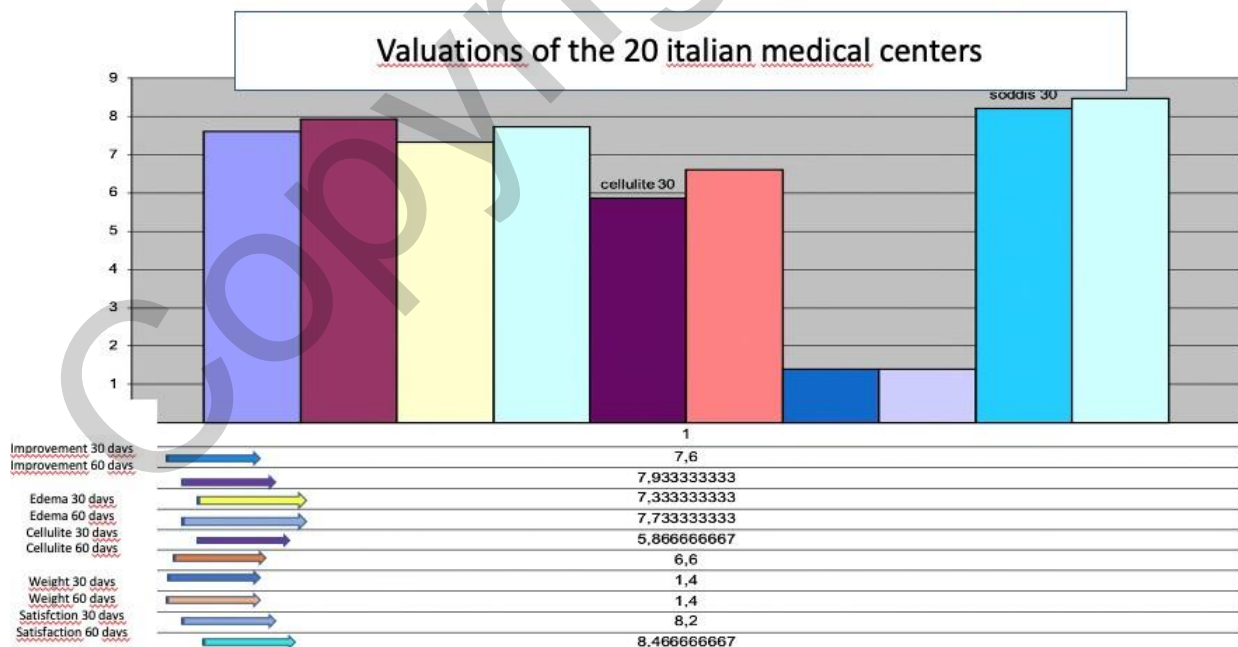


Fig. 7. Results of treatments performed by medical centres in 2007/2008 that reveal an excellent response on lymphatic stasis with Scala VAS.

The reduction of the subcutaneous thickness at the trochanteric and supramalleolar level was also detected in the monitored group of 16 patients in

the Documentation Center in Aesthetic Pathologies of Arezzo (Fig. 8).

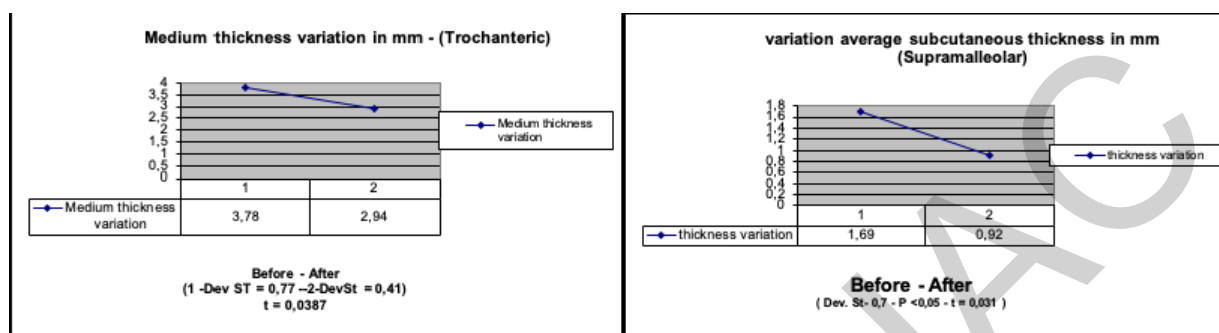


Fig. 8. Reduction of supralleolar and trochanteric thickness evaluated with ultrasound (Courtesy Prof. Bacci).

A specific study on the treatment of "hard and fibrous lymphedema" performed with the "Endosphères" method at the University of Chieti demonstrated the typicality of the "compressive microvibration" methodology in significantly reducing the thickness of subcutaneous tissues affected by lymphatic stasis in the twenty patients treated (16).

In his conclusion, Professor Raul Saggini, director of the Postgraduate School of Physical Medicine and Rehabilitation at the "G. D'Annunzio University" of Chieti, reported "the presence of a significant reduction in edema associated with a significant reduction in painful symptoms typical of patients suffering from panniculitis or erythema nodosum".

The innovative approach of the "Endosphères" system in performing a "vibration lymphatic drainage" showed optimal results in patients with

severe secondary lymphedema, who in the study of Professor Saggini were divided into three groups: 9 patients with stage 2 lymphedema, 7 patients with stage 3 and 4 patients with stage 4.

All patients were treated with 2 weekly sessions of Endosphères draining therapy for 24 weeks, associated with rehabilitation in water from the third month, depending on the severity.

The results, evaluated clinically and by VAS visual analogue scale, showed that in the first and second group absolutely optimal responses were observed regarding the subjective evaluation of painful symptoms, which had reduced to 3 VAS after 18-20 sessions, while in the third group had reduced to 6 VAS after 20 weeks.

All patients reported pain reduction and edema improvement, with a 5-8 cm difference compared to the healthy contralateral and with soft tissue ultrasound which showed a clear reduction in the

thickness of the subcutaneous tissues.

Pain reduction

Cellulite can express itself in different forms linked to as many etiological and pathophysiological pictures, clinically two large groups of cellulite can be described, classified as "Hot" or "Cold" (17).

Hot cellulite is the typical "adipose cellulite" characterized by an increase in subcutaneous adipose tissue. It basically represents juvenile cellulite or that of overweight girls. Cold cellulite is above all "edematous cellulite" and "fibrous" cellulite, both characterized by a reduction in microcirculation, alteration of the plasticity of the interstitial matrix and lymphatic edema with an increase in toxic substances. It is the typical cellulite of girls who take the estrogen-progestogen pill, who are sedentary and who have swollen legs in the evening due to venous and lymphatic insufficiency. It is also the cellulite of older women with fibrous and hypoxic cellulite.

Cold cellulite is mainly characterized by coarse adipose aggregates with the connection of the septa and evolutionary fibroedema of the tissues. Above all, there is a constant pain in the thigh. Daily practice has shown that especially this type of evolutionary fibroedematous cellulite responds better to "compressive microvibration".

In these patients, the methodology seems to act specifically also on the receptors that regulate pain, with consequent reduction of the inflammatory response (18, 19). Thanks to the compressive

microvibration induced by the methodology, these "mechanoreceptors" undergo a kind of "desensitization" that leads to the reduction or elimination of pain in a short time. Associated with the best oxygenation, the activation of receptors and energy points allows the opening of calcium channels and the reduction of tissue inflammation, therefore the reduction of pain and evolutionary fibroedema, creating a kind of therapeutic synergy that can be well exploited, for the painful forms of cold cellulite, for the pain of lymphedema, and in traumatology and sports medicine (20).

A study carried out by the Board of Physical and Rehabilitative Medicine of the University of Chieti, presented at the Sports Medicine congress in June 2005, reported the particular pain-relieving activity of the methodology that can be used in almost all injuries types and muscle pain (21).

Bellomo and Saggini conclude that the analgesic activity is due to the action on the skin mechanoreceptors stimulated by the micro percussion regimen used, therefore by the frequency used.

Working in a "flutter range" with vibrations that were around 40\50 Hz, the action of Endosphères is exerted on the mechanoreceptors of the dermis (Meissner's Corpuscles), working instead in the "vibration range" with frequencies over 100 Hz. they stimulate the deeper mechanoreceptors (Pacini's Corpuscles).

The mechanical action is thus transformed into a desensitizing and sedating effect on the hyperexcitability of the sensory and motor nerves, with consequent analgesic activity. This analgesic activity of the Endosphères treatment was also found in the medical centres that carried out the preliminary studies and agreed with the observations made in the monitored group using

the Breu- Marshall Pain-test, which showed that a clear reduction in cellulitic or lipodystrophic tissue pain is always evident after the Compressive Microvibration treatment, as an expression of a better oxygenative metabolism and less presence of toxic and inflammatory substances (22, 23) (Fig. 9).

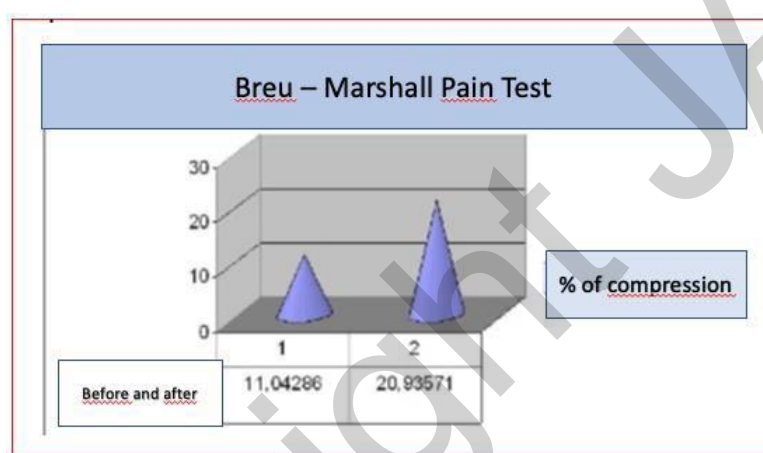


Fig. 9. Pain reduction assessed with Breu Marshall's Pain Tes (Courtesy prof. Bacci).

Toning and remodeling

The so-called "orange-peel" of cellulite of the lower limbs, understood as the aging process of the subcutaneous matrix/ connective tissue system, as well as of the adipose tissue and the skin dermoepidermal structure, is characterized by evolutionary fibroedema involving all tissues, from the fascia to the skin with retraction of the connective septa and alteration of the quantity and quality of adipose tissue.

All this causes the typical orange-peel effect with a reduction in skin thickness and subcutaneous panniculus, so that laxity of the tissues is also

highlighted, with the "containing" becoming larger than the "content", in a series of alterations starting from the reduction of oxygenation and cellular purification up to altered immune responses. Especially in constitutionally and functionally predisposed cases, these ageing processes lead to tissue failure that alters the contour and harmony of the body (24-27).

In female evolutionary cellulite fibroedema there is always an alteration of the aesthetic appearance and the silhouette, which is why we are talking about aesthetic pathologies, leaving only the

imperfection to non-medical professional beauty treatments. The "Endosphères" method works with the principle of "microvibration-microcompression-elastic response" which uses the muscle band and muscle tone as active resistance to obtain the microcompression of adipose aggregates and fibrous septa which are thus broken down and made less fibrosclerotic.

This mechanism of action, which exploits the rotating spheres and tissues of the patient, allows skin and connective tissue remodeling with physiological tissue restructuring obtained thanks

to the improvement of vascular, metabolic, purifying and regenerating activities. The bundle-muscular activities can also be exploited in sports medicine, both in traumatology and in the preparation of athletes, as well as for faster muscle rehabilitation. One of the first effects is vascularization and muscle toning that the patient refers to as a sense of "muscle reactivation", it is the result of vascularization and tissue reactivation given by compressive microvibration (28-31) (Fig. 10).

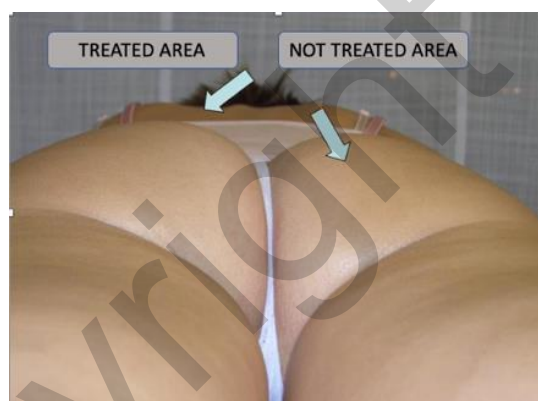


Fig. 10. Tissue toning effect due to vascularization and *Endosphères* stimulation (Courtesy Fenix).

Preliminary clinical observations indicated the "Endosphères" methodology as technique of choice in all forms of cellulite, lipoedema and

lipodystrophy, with its greatest indication in adipose-edematous cellulite and in fibroadipose cellulite (32-36) (Fig. 11).



Fig. 11. Cellulite improvement after *Endosphères* treatment (Courtesy Bacci).

It is also interesting to note the action of the methodology in the most difficult situations, such as in aesthetic adipose-tissue pathologies of the

chest or hips, in association with other methods, such as liposuction, laserlipolysis and an adequate diet (Fig. 12).



Fig. 12. Remodeling effect with integrated methods (Courtesy Bacci).

Results

Every medical or physiotherapeutic treatment causes effects on the tissues, which is why in the daily practice monitoring of the tissue state is carried out every six sessions. This time derives from the variations that tissues present during the treatments and therefore from the need to adapt treatmentss to the new situations. In the so-called

cellulite, the visual response is certainly the slowest to appear compared to the data collected with other tests.

In 2003, the BIMED-TCD Code was presented, as a simple practical test that, in cellulite, evaluates the vascularization of the tissues, the state and visibility of the ‘orange-peel’ skin and the

tenderness of the tissues, to finally have a number whose variation indicates the response obtained with the treatment performed. The possibility of

having a "number" constitutes the value of the test (37-41).

The TCD Code

The "TCD Code", intending "Temperature - Clinical - Pain", integrates the clinical diagnosis by investigating the vascularization, degenerative evolutions and painful symptoms of tissues affected by cellulite.

The "T Factor" investigates the variation of vascularization and skin temperature with a liquid crystal plate system or with Anther Chamber that detects changes in hemoglobin. In young and healthy subjects, in standard conditions and in an environment without humidity, the skin's vascularization is regular and uniform, the

gradients reflect the distribution of the blood supply and, above all, there are no cold areas where microcirculation is reduced.

By identifying 25 different thermographic pictures, we detect different vascular situations, the scale from 0 to 3 means normality (T0), from 4 to 7 means initial microcirculatory alteration (T1), the scale from 8 to 13 means venulocapillary stasis (T2), the values to be 14 to 19 mean cold zones with hyperthermic "black holes" (T3), ending with values from 20 to 25 which signify clear connectivization and liposclerosis (T4) (Fig. 13).

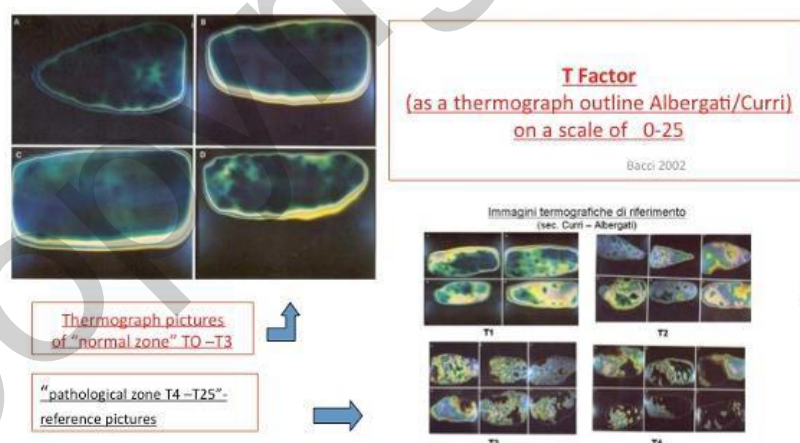


Fig. 13. Thermographic rating scale for Factor T in the TCD Code (Courtesy Bacci).

"Factor C" investigates the type of orange peel identifying nine different states referable to skin imperfection with a special dedicated VAS scale, offering a final picture useful to have the perception that the patient has of his imperfection:

C1 – Orange peel skin invisible to the naked eye

C2 – Orange peel skin noticeable only when palpated

C3 – Orange peel skin visible only when the patient is seated

C4 - Orange peel skin just visible to the naked eye
 C5 - Orange peel skin clearly visible to the naked eye

C6 - Orange peel skin very clearly visible to the naked eye

C7 - Orange peel skin very clearly visible to the naked eye and compacted

C8 - Orange peel skin very clearly visible to the naked eye and fibrous

C9 - Orange peel skin very clearly visible to the naked eye accompanied by hypotrophic tissue

The "Factor D" investigates the pain symptom instead, identifying seven different states characterizing the symptoms expressed by the adipose and tissue panniculus of the subcutis. These indications are very useful to the definition of therapies and for prevention of complications. They are consequently essential for the therapeutic

strategy because they divide the evolved female fibroedema of "cellulite" into two large groups:

- Pain-free cellulite
- Painful cellulite

This classification, when associated with the definition of hot and cold cellulite, easily identifies and indicates causes, therapies and prognosis for improvement.

D0 - Cellulite not painful when pinched

D1 - Cellulite slightly painful when pinched

D2 - Cellulite painful when pinched

D3 - Cellulite slightly painful when compressed

D4 - Cellulite painful when compressed

D5 - Cellulite very painful when compressed

D6 - Cellulite painful without compression

D7 - Spontaneously painful cellulite accompanied by a sensation of heaviness in the legs

Ultrasonic Pain Test (Breu-Marshall test)

In cellulite and lipodystrophy, pain is caused by the state of tissue acidosis, by the excess of free radicals and by the inflammatory activity resulting from the stasis of toxic substances and lymph.

To increase the pain assessment, a specific examination can be used to identify and quantify the pain symptom. We can use a 10-13 MHz probe of the ultrasound or ecocolordoppler. The soft layers of the thigh are studied anteriorly and the thickness of the dermoipodermic layer from the skin to the fascia is detected, connecting it to the painful response evoked by the compression of the

probe (42-44).

The subcutaneous is usually poor in ultrasonic echoes, ultrasound diagnostics searches for the point of pain expression using the compression of the probe on the tissues, then the thickness of the compressed tissue is studied, whose numerical variation after treatment will indicate any improvement or the worsening of the pain symptom: the greater the compression necessary to evoke the pain, the greater the improvement obtained with the therapies (Fig. 14).

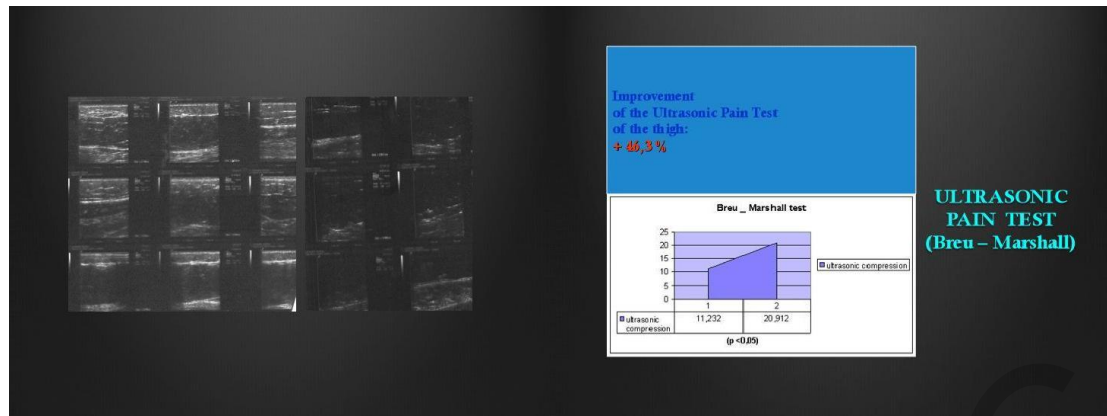


Fig. 14. Ultrasonic Pain Test nel Codice TCD (Courtesy Bacci).

TCD Number

Utilising the sum of the numbers obtained from the "TCD factor", a final number is obtained, which is between 5 and 45, that indicates the state of the cellulite dermohypodermic pathology and which is ultimately essential in the control of treatments, also proving to be extremely useful in the scientific or legal medical field. In Figure 15, four treatments are compared (Phytotherapy solely, Placebo, Physical Therapy, Phytotherapeutic plus Physical Therapy) which are evaluated with TCD

code showing significant differences in "Before / After", it is interesting to note that all patients averaged around the TCD number 20/21, which indicates a second stage edemato-fibrous cellulite. In patients treated with phytotherapeutic drug only, the TCD 20 became TCD 13 whilst in patients treated with Phytotherapy drug plus mechanical physiotherapy, the TCD fell to TCD 8.8 which is in the early stages (Fig. 15).

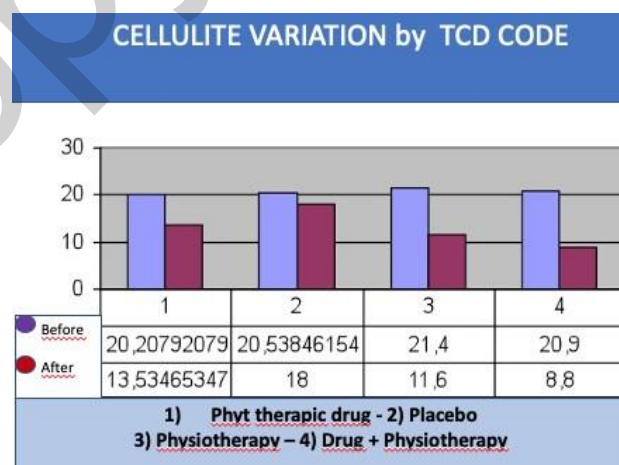


Fig. 15. Results of treatments evaluated with the TCD Code (Courtesy Bacci).

Despite its simplicity, the TCD Code has interesting aspects that can help in daily medical practice to evaluate the results obtained. Currently, this code has been updated as the TCDE Code because the evaluation of the improvement of edema of the lower limbs has been added. Consistent with the observations made in other

studies, even the medical judgments detected on the sample group of patients showed good tolerability (9.93 on the VAS scale) and efficacy (7.18 on the VAS scale), no complications or side effects were observed such as capillaries, hematomas, bruises, infections, skin sagging (Fig. 16).

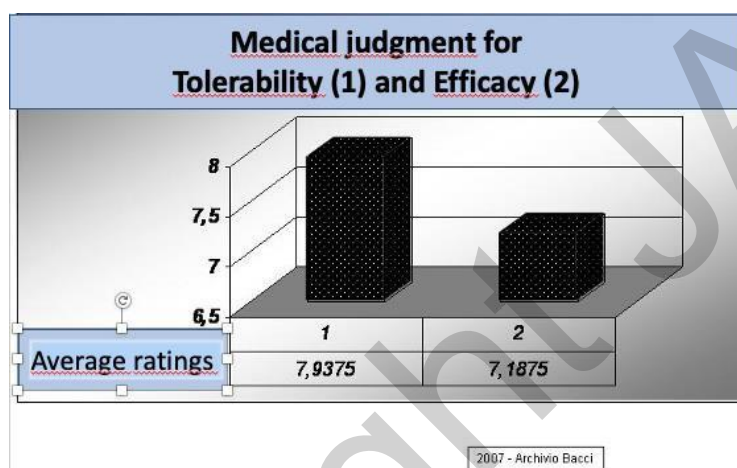


Fig. 16. The graph demonstrates tolerability and efficacy with the VAS scale in the treatment of cellulite with Endosphères (Courtesy FenixGroup).

The preliminary data referring to a clinical experience of about 3 years on patients suffering from different types of cellulites offered good

results with the "Compressive Microvibration - Endosphères" methodology.

Discussion

The scientific rationale filed with the Board of Physicians and Surgeons of Arezzo in 2008 reported the conclusions referring to the clinical observations made in different locations by doctors of various specialties, supported by studies carried out in universities or medical control centres.

The objective of the document was the "recapitulative photograph" of the relationship

between the mechanism of action of the new non-invasive strategy of Endosphères Compressive Microvibration and the tissue changes detected in patients treated for cellulite in the various forms and stages, all to support the scientific value and the claims made.

In summarizing the activities and results of the various medical centres that followed the

preliminary tests in the multicentre, two hundred patients were followed, recording some results referable to tolerability, efficacy and patient satisfaction, especially in the reduction of pain, edema, heaviness and cellulite blemish.

At the same time a medical control centre monitored sixteen patients with the same treatments. Comparing the various results, it was possible to conclude in the positive action of the new non-invasive strategy in the treatment of cellulite and lipolymphedema.

In 2008 this new method constituted a real revolution in non-invasive clinical and dermocosmetic treatments, both in terms of therapeutic strategy and in terms of its conception and technical implementation, but it was not considered a conclusive experience.

In fact, that first scientific rationale concluded: "Certainly the future will require other studies and

other more in-depth clinical observations in the various sectors, but it can certainly be concluded that this method will constitute a new era in the treatment of the different forms of cellulite and lipolymphedema, placing itself as a basic therapy around which all other possible methods aimed at specific alterations can revolve".

With the strength of twenty years of experience and clinical observations, and in the light of modern knowledge, it can be deduced that the Endosphères Compressive Microvibration has continued to demonstrate the value of its actions obtainable with the rotating silicone spheres in the various protocols and in the various frequencies, placing itself today as a reference point for oedematous, adipose or lipodystrophic clinical and aesthetic pathologies of the lower limbs, body and abdomen.

Conclusion

In order to exist, life needs oxygen, hydrogen and energy. A good vascularization and a good oxygenation allow the mitochondrion to produce that energy that ignites the typical depurative, metabolic, plastic, and immune activities of the cells.

The vascularization especially favours the right temperature that activates all the physiological vital reactions present in the matrix, necessary especially to remove lymphatic stasis and toxins and maintain correct cellular oxygenation, but if

the tissues are hypoxic and infiltrated by substances to be eliminated, the inflammatory and degenerative phenomena typical of the ageing processes of all tissues are activated.

Cellulite is a symptom that indicates that something begins to fail, but over the years it becomes a real aesthetic pathology, and the pain symptom also appears. The beginning of cellulite lies in the interreaction between "arteriole-adipocyte-matrix-lymphatic", the modern Western diet rich in sugars, dyes and hormones, brings a

large number of substances to be eliminated in the fundamental substance of the matrix that requires ever greater quantities of water, oxygen and energy to dispose of them.

The passage of time and the continuation of stressors change the temporary functional lymphatic stasis into lipolymphedema, with an increase in tissue acidity, protein glycation, iron displacement, an increase in free radicals and oxidative stress that make the flogistic-degenerative processes evolutionary, typical of female evolutionary fibroedema. The main problem of the ageing processes always lies in the reduction of cellular oxygenation with a reduction in energy production due to reduced activity of the mitochondrion and the adipose cell. For these reasons, a precise basic physiotherapeutic treatment, combined with a proper purifying deacidifying diet, is always the best prevention and the basis of any corrective treatment (45-50).

All patients treated with Endosphères have always shown satisfaction right from the first sessions, with significant improvement in painful symptoms and hypersensitivity of cellulite tissues, with improvement in orange-peel and tissue compactness, and it is interesting to observe how there is a tendency towards improvement even after a few weeks of stopping treatment.

It is a trend that not only improves the quality of life of patients but opens up new windows of reflection on the "cell regenerative activities" of the method, which are certainly favoured by particular frequencies and by the stimulation of trigger points

or TuiNa created by the rotating microspheres. Recently studies have begun on the Endosphères treatment targeted at this new aspect of regenerative medicine, but it can be said that if the Compressive Microvibration promotes a significant and demonstrable improvement of cellulite tissues in a subjective and objective way that lasts for several months, it means that a complex mechanism of action is implemented which counteracts the causes of the various phlogistic-degenerative processes, definable in the reduction of microcirculation, in the reduction of cellular metabolic activity and in the plastic immune alterations of the matrix.

Compressive Microvibration has also been shown not to act on adipose tissue causing lipoclasia with cell breakdown and release of free fatty acids in the tissues because it promotes a progressive physiological superficial lipolysis that is associated with the connective and dermal restructuring of tissues and skin. The Endosphères methodology has certainly been a revolution in the "treatment of orange-peel and adipose cellulite", and rightly is still positioned both as a preventive therapy and as a basic corrective therapy for all forms of cellulite, which may be associated in the cases indicated with other necessary medical therapies.

The new treatment proposal "Endosphères" for orange-peel and cellulite in its different forms responds to current scientific knowledge and is suitable for the current demands of patients. Today it is also a reference point for oedematous, adipose or lipodystrophic clinical and aesthetic pathologies

of the lower limbs, body and abdomen.

References

1. Collis N, Elliot LA, Sharpe C, Sharpe DT. Cellulite treatment: a myth or reality: a prospective randomized, controlled trial of two therapies, Endermologie and aminophylline cream. *Plast Reconstr Surg* 1999; 104(4):1110-4.
2. Chang P, Wiseman J, Jacoby T, Salisbury AV, Ersek RA. Noninvasive mechanical body contouring: (Endermologie) a one-year clinical outcome study update. *Aesthetic Plast Surg* 1998; 22(2):145-53.
3. Bellomo RG. Technological innovations in the treatment of lymphedema. Lymphology course at the G. D'Annunzio University of Chieti, 2012.
4. Saggini R, Di Pancrazio L, Iodice P, Bellomo RG. Treatment of secondary lymphedema using Endospheres vibration lymph drainage. Chair of Physical and Rehabilitative Medicine, University Center of Sports Medicine University of Chieti, 2007.
5. Bordoni B, Sugumar K, Varacallo M. Myofascial Pain. In: StatPearls [Internet]. Treasure Island (FL) 2021.
6. Chu J. The local mechanism of acupuncture. *Zhonghua Yi Xue Za Zhi (Taipei)* 2002; 65(7):299-302.
7. Iannaccone M. The TuiNa points. in Bacci PA, "Cellulitis 2012". Officine Editoriali Oltrarno, Firenze, 2012:139-145.
8. Merla A. Tele-thermographic survey report for the verification of the cutaneous thermal effects of the Endospheres Therapy treatment. ITAB University of Chieti, 2007.
9. Bacci PA, Bozzelli S, Leonardi S, Vannuccini S, Bellomo RG, Saggini R. Vascularizing action of the compressive microvibration endospheres. *Journal of Applied Cosmetology* 2021; 39(2):61-69.
10. Binazzi M, Grilli-Cicioloni E. About the so-called cellulite and edematous fibrosclerotic dermo-panniculopathy. *Ann It Derm Clin Sper* 1977; 31:121-125.
11. Bacci PA. Physiopathology of FEF. in Bacci PA, Cellulitis 2012, Officine Editoriali Oltrarno, Firenze, 2012; 79-113.
12. Albergati FG, Bacci PA, Mancini S. La matrice extracellulare. Minelli Editore, Arezzo 2004.
13. Pishinger A. Matrice e regolazione della matrice. Ed. Haug Int, SIMF, Milano, 1996.
14. Bacci PA. The compressive microvibration with "Endospheres AK55". Scientific rationale and clinical observations. Order of Physicians and Surgeons of Arezzo, 2008.
15. Bacci PA, Leonardi S, Vannuccini S, Frappi S, Rampino G, Bellomo RG, Saggini R. Thermographic and clinical data (TCD Code) in the evaluation of cellulite treatment by Endospheres Therapy. *Journal of Applied Cosmetology* 2021; 39(2):60-8.
16. Saggini R, Bellomo RG, Di Pancrazio L, Monteleone N, Lessiani G, Lolli A. Comparison of therapies in the treatment of localized lipodystrophies and primary lymphedema, University of G. D'Annunzio of Chieti, 2007.
17. Bacci Goldman M, Hexsel D, Leisbahoff G, Bacci PA, Angelini F. Cellulite: pathophysiology and treatment. Taylor & Francis Editor, New York, 2006.
18. Saggini R, Bellomo RG, Dodaj I. Treatment of localized lipodystrophies. University of G. D'Annunzio of Chieti, 2011.
19. Bacci PA. Le celluliti. Minelli editore, Arezzo, 2000.
20. Saggini R & Coll. Sports physical activity and neuromuscular pathologies. Proceedings of the Sports Medicine Congress, University of Chieti, June 2005.
21. Bellomo RG, Iodice P, Saggini R. Endospheres method in sports muscle recovery. Degree Course in Motor Sciences, University of Chieti, 2008.
22. Bacci PA, Saggini R. Vascular action and pain reduction by compressive microvibration. International Congress of Italian Society of Aesthetic Medicine SIME, Rome, 2022.

23. Distant F, Bacci PA, Carrera M. Efficacy of a multifunctional plant complex in the treatment of the so-called 'cellulite': clinical and instrumental evaluation. *Int J Cosmet Sci* 2006; 28(3):191-206.
24. Curri SB. Aspect morphohistochimiques du tissu adipeux dans la dermohypodermose cellulitique. *J Med Est* 1976; 5:183.
25. Curri SB. Lymphedema, lipedema, liposclerosis, a nosological question. *La Medicina Estetica* 1984; 8-10.
26. Avram MM. Cellulite: a review of its physiology and treatment. *J Cosmet Laser Ther* 2004; 6(4):181-5.
27. Goldman M, Bacci PA, Hexsel D, Angelini F. *Cellulite: pathophysiology and treatment*. Taylor & Francis, New York, 2006.
28. Curri SB. Liposclerosis and microcirculation, *La dermoestetica* 1990; 1:6-7.
29. Kaminer MS, Coleman WP 3rd, Weiss RA, Robinson DM, Coleman WP. Multi center pivotal study of vacuum assisted precise tissue release for cellulite. *Dermatol Surg* 2015; 41(3):336-47.
30. Saggini R. Endospheres, protocols. First level clinical-experimental degree course in Physiotherapy, University of Chieti, 2008.
31. Mezzogiorno A. Compressive micro-vibration in the treatment of facial wrinkles and skin relaxation. Course in Aesthetic Medicine, International Congress of Italian Society of Aesthetic Medicine SIME, Rome, 2012.
32. Diffidenti B. The innovation of the spheres. International Congress of Italian Society of Aesthetic Medicine SIME, Rome, 2014.
33. Maullu G, Pirino A. Functional treatment of cellulite with compressive microvibration: from experimentation to clinical practice. Medical Degree Thesis in University of Sassari, 2019.
34. Follador E, D'Angelo D, Marini F. Compressive microvibration in lymphedema and lipoedema. International Congress of Italian Society of Aesthetic Medicine SIME, Rome, 2007.
35. D'Angelo D, Marini F, Bacci PA, Saggini R. Compressive microvibration in the cellulite treatment: retrospective study. *Journal of Applied Cosmetology* 2021; 39(2):44-59.
36. Bellomo RG. Technological innovations in the treatment of lymphedema. Course on Lymphedema, University of G. D'Annunzio of Chieti, 2012.
37. Bacci PA. TCD Code, a new classification for cellulite. CIF Italian College of Phlebology Congress, Udine, 2003.
38. Bacci PA. TCD Code. International Academy Cosmetic Surgery Congress, Varna 2006.
39. Bacci PA. BIMED-TCD Code. International Congress of Italian Society of Aesthetic Medicine SIME, Rome, 2003.
40. Bacci PA. Code TCD, nueva clasificacion por la cellulite. Sociedad Española de Medicina y Cirugia Cosmetica, Sitges, 2004.
41. Bacci PA. Clinical therapeutic classification: BIMED TCD. in Goldman M, Hexsel D, Bacci PA Leibashoff G. *Cellulite*. Taylor & Francis, New York 2006; 1:115-141.
42. Bacci PA. BIMED-TCD Code. in Bacci PA, *Cellulitis 2012, Physiopathology and treatments*, Officine Ed. Oltrarno, Firenze, 2012.
43. Breu FX, Marshall M. Neue Ergebnisse der duplexsonographischen Diagnostik des Lip- und Lymphödems (Kompressionssonographie mit einer neuen 13-MHz-Linearsonde). *Flebologia* 2000; 29(05):124-128.
44. Marshall M. *Praktische Duplex-Sonographie*. Springer Nature, Berlino, 1996.
45. Curri S. *Microangioangiologia*, Inverni della Beffa, 1974.
46. Bass LS, Kaminer MS. Insights into the Pathophysiology of Cellulite: A Review. *Derm Surg* 2020; 46 Suppl 1(1):S77-S85.
47. Zerini I, Sisti A, Cuomo R, et al. Cellulite treatment: a comprehensive literature review. *J Cosmet Dermatol* 2015; 14(3):224-40.

48. Tokarska K, Tokarski S, Woźniacka A, Sysa-Jędrzejowska A, Bogaczewicz J. Cellulite: a cosmetic or sistemi issue?. *Postepy Dermatol Alergol* 2018; 35(5):442-446.
49. Wang CH, Wu SB, Wu YT, Wei YH. Oxidative stress response elicited by mitochondrial dysfunction: implication in the pathophysiology of aging. *Exp Biol Med* (Maywood) 2013; 238(5):450-60.
50. Bacci PA. *Impara a depurarti*. Youcanprint, 2017.

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