Post Market Clinical Follow-up

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Applications of cold, warm and thermal shock into:
1. the Physiotherapy and Sports Medicine about painful and inflammations disorders of muscles, tendons and bone;

2. the Aesthetic field in treating undesired fat, cellulite, body and facial toning.

Introduction

CRYO T-SHOCK represents a new approach into the treatment of several human pathologies.

Cold and hot represent the main natural energy which could provoke a wide range of direct and indirect actions over the different cellular layers. When cold and hot are correctly applied, under the control of the operator which manually set each parameter with reference to the patient's sensitivity and feedback, actions of cold and hot would be capable to generate therapeutic benefits and a physiological response of human body.

Into the physiotherapy and rehabilitation medicine, from the existing bibliography and clinical experiences, from one side we know about the positive effects of hot in provoking diathermy; from the other side, we know about the benefits of cold in pain relief and in stimulating vasocostriction for reducing inflammation and edema.

Into the beauty applications, bibliography is full of experiences concerning property of cold in destroying undesired fat cells (apoptosis) and we know that hot is capable to stimulate collagen.

Introduction

Into the field of Physical Therapy, hot and cold treatments are currently the most important and widespread response to combat pain and inflammation.

Thermotherapy energy is one of the simplest energy sources to be applied into the physiotherapy field and permits to provoke several benefits, thanks to the physiological effects coming from hot and cold.

Dynamic and controlled thermal shock is a form of energy with proven biological effectiveness, which is administered and subtracted in a controlled and combined manner for quick pain relief and complete functional recovery. The controlled combination of vasodilatation and vasoconstriction induced selectively in tissues allows fully exploiting the strong effects of the temperature changes imposed locally. Thermal Shock is effective in the early stages of rehabilitation because it provides quick pain relief, reduces swelling, improves joint mobility and allows insertion in the later stages

Background

Our activity in asking to two different selected Pilot Groups of Clients to apply CRYO T-SHOCK in treating their patients for collecting useful clinical evidences into the applications of cold and hot. Clinical approach is basically coming from the existing and accepted International background in using cold and hot in various physiotherapy pathologies where we may find pain, edema and inflammation.

Also, in treating cellulite as an inflammatory and water retention disorder, exchange between cold and warm may provoke benefits in improving local blood flow, increasing oxygen and reducing inflammation.

Background

We also generally know from all clinical evidences, that cold and the fast exchanges between cold and warm provoke vasodilatation and vasocostriction which provokes muscle spasm and relaxing. This is why, this technique is also useful for stimulating skin toning.

Last but not least, International bibliography and evidences are attesting capability of cryotherapy to destroy (apoptosis) fat cells while a temperature of around 12 to 14° C has been reached.

Background

The defense mechanism triggered to counteract the cold, stimulates circulation blood, the endocrine system, the immune system and the central nervous system with anti-inflammatory, analgesic, pain-relieving properties, anti-metabolic and antidepressant. «The cold causes the release of acetylcholine and noradrenaline from the neurons of the sympathetic system which inhibit the transcription factor NF-kB at the immune system level, ie the center of the inflammation - it enters in detail Lombardi -. Thus the inflammatory mediators "downstream" are also blocked and the production of free radicals and adhesion molecules (the proteins located on the cellular surface) that activate the escape of white blood cells in the tissues and therefore the on-site production of the inflammatory stimulus . In addition, the cold causes vasoconstriction and therefore limits inflammation and directly inhibits the enzymes involved in tissue destruction, a phenomenon common to all inflammatory processes.
The thermal part is effectively used to create the thermal shock, creating sudden and sudden excursions between heat and cold, where the cryogenic part is the predominant part of the treatment, while the thermal part is necessary to create the shock and give rise to all those positive interactions we have described above as belonging to the cold.

Background

Summarize of know and reported action of cold and warm

- Benefits on painful areas
- It acts on inflammation
- Reduces recovery times
- It acts on cellulite more properly and on PEFS (panniculopatia edemato fibro sclerotica)
- Stimulates apoptosis, fat cell removal
- It acts on the mechanisms of aging of the face
- It acts on the reduction of edema after an aesthetic surgery

Background

Even if the majority part of the existing literature and bibliography is concerning just cryotherapy (cold) or just diathermy (hot), because at the moment there is no further devices capable to deliver both cold and hot, we objectively have the opportunity to get all existing evidences as a very useful experience for confirming the therapeutic opportunity to offer a single device capable to generate both hot and cold, for provoking all benefits of both energies while they are controlled, manually made, delivered with care and useful recommendations for avoiding collateral effects and excluding contraindicated conditions.

Aim of the PMFC

It’s our intention to collect all useful information and details coming from a Pilot Group Physiotherapy and/or beauty centers using CRYO T-SHOCK for getting the following information:

- attesting general capabilities and benefits of cryotherapy, diathermy and thermal shock;
- range of useful applications;
- general parameters to be used;
- possible collateral effects;
- contraindications.

Pilot Group

Two different Pilot Groups of Customers have been selected:

About applications in physiotherapy and rehabilitation:

- Poliambulatorio Medeor
- Fisioteck Uboldo
- Fisioteck Cislago
- Centro Medico Ape Gaia

About applications in beauty field:

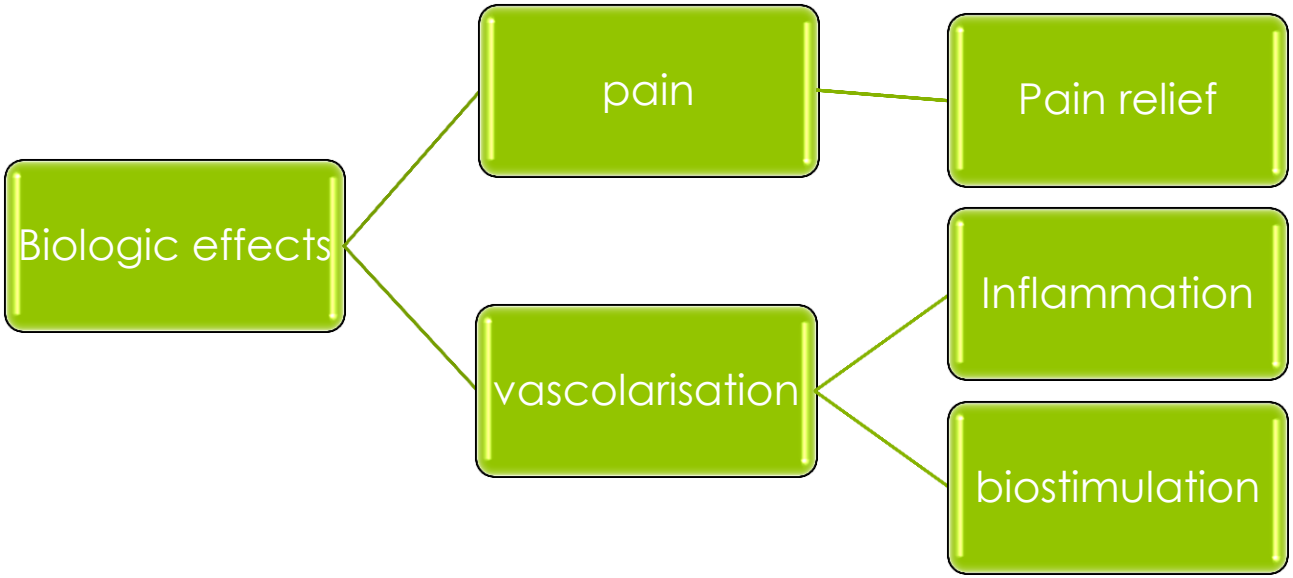
- Poliambulatorio Adec
- Studio Ponzano
- Dr. Neri
- Lumat
- Dr. Aprile

Pilot Group

For each group of patients included into the research some objective personal data concerning each treated person have been considered; the patients would be females and males starting from 18 years old.
Further details and patient's conditions have been considered for each group and are mentioned into each section of the PMFC.

Clinical Evidences

Physiotherapy principles



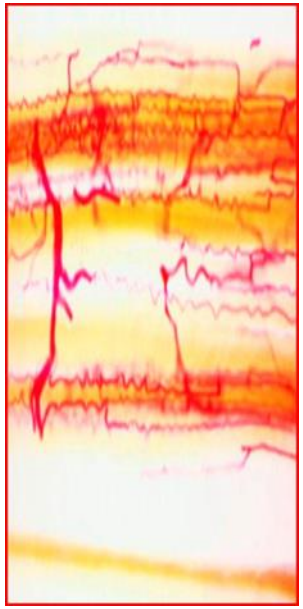
Shortly, the research carried out in sports, physics and rehabilitation medicines concerns the properties and universally known effects of heat and cold applied to the human body and which are graphically shown above.

Physiotherapy principles

pain

- Nociceptors action with changing of membrane cells able to avoid potential action causing making pain;
- Inhibition of centripet conduction of pain due to action of cold over the nociceptors;
- Activation and deliver of endorphines and encephalines reducing pain feeling;
- Activation of Merkel's corpuscles (pressure's receptors) with anatgonist reaction of stress based on catecolamines.

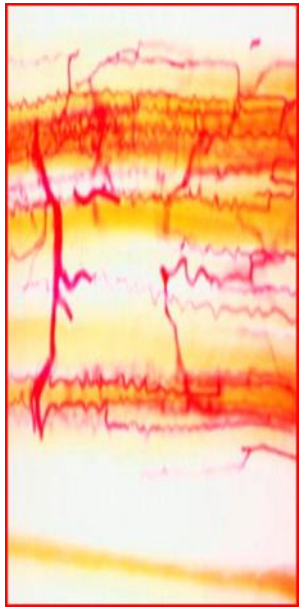
vascolarization



- At the tissutal level some biomolecular modifications come from vasodilatation and vasocontriction process such as the neoangiogenetic response passing from ESAF (Endothelial Stimulating Angiogenic Factor) Citotossic (free radicals) Antiflogistic and neuromodulating (> permeability of assonal membrane with consequent depolarization).

vascolarization

- It's reasonable to think that re-vascolarization should be related to teh following actions;
- neocapillarogenesis coming from the repairing of basal membrane and due to the flow of endothelial cells into the interstitial spaces;
- it makes easier and faster metabolic changes into the affected tissues, stimulating reparative processes and elasticity process of the soft tissue.



Physiotherapy principles

The biological modifications induced by cryothermalkinetics, combined and associated with each other, have the following therapeutic effects:

- Anti-inflammatory effect: because it slows down cellular metabolism which in turn reduces the production and release of chemical inflammatory mediators (histamines, bradykinin, serotonin);
- Anti-edema effect: cryo thermal shock is very effective in the treatment of edema, especially post-traumatic edema. The anti-edema effect is correlated to the anti-inflammatory action and vasoconstriction, which limits extravasation of blood tissues.
- Analgesic effect: cold and hot notoriously reduce pain because they are capable to inhibit nerve endings, slowing down nerve conduction of the algogenic impulses and reducing local inflammations.
- Muscle-relaxant effect: fast exchanges of cold and hot induce a slow muscle stimulation. This why, fast and prolonged exchanges between cold and hot reduce muscle tone and spasms. To obtain these effects, prolonged applications are necessary; whereas, short applications act on the nociceptors which cause reflex muscle contraction.

Physiotherapy principles

The physiological responses underlying the therapeutic effects of heat include an increase in blood flow, increase in extensibility of collagen tissues, relief from muscle spasms, reduction of pain, reduction of inflammation and edema. The effects of cryotherapy are: vasoconstriction with reduction of blood flow, pain relief, reduction of edema, reduction of contraction, the metabolism and release of enzymes and histamines.

Dynamic and controlled thermal shock is a form of energy with proven biological effectiveness, which is administered and subtracted in a controlled and combined manner for quick pain relief and complete functional recovery. The controlled combination of vasodilatation and vasoconstriction induced selectively in tissues allows fully exploiting the strong effects of the temperature changes imposed locally.

Thermal shock is effective in the early stages of rehabilitation because it provides quick pain relief, reduces swelling, improves joint mobility and allows insertion in the later stages. Significant temperature variations stimulate reparation of microcirculation, connective tissues, tendons and joints, resulting in a remarkable pain-relieving effect.

Rapid thermal shock has a direct action on deep tissues, by hyper-stimulating deep tissues it promotes tissue repair, including scars, and greatly aids movement.

Evidences

Deatils coming from the Pilot Group

Pilot Group

The group of patients are women and men, at least 18 years old and for each of them, the following personal and anamnestic data have been collected:

- Sex
- Age
- Articulation
- Pathology
- Symptoms: pain (vas scale), swelling, edema, heat, redness

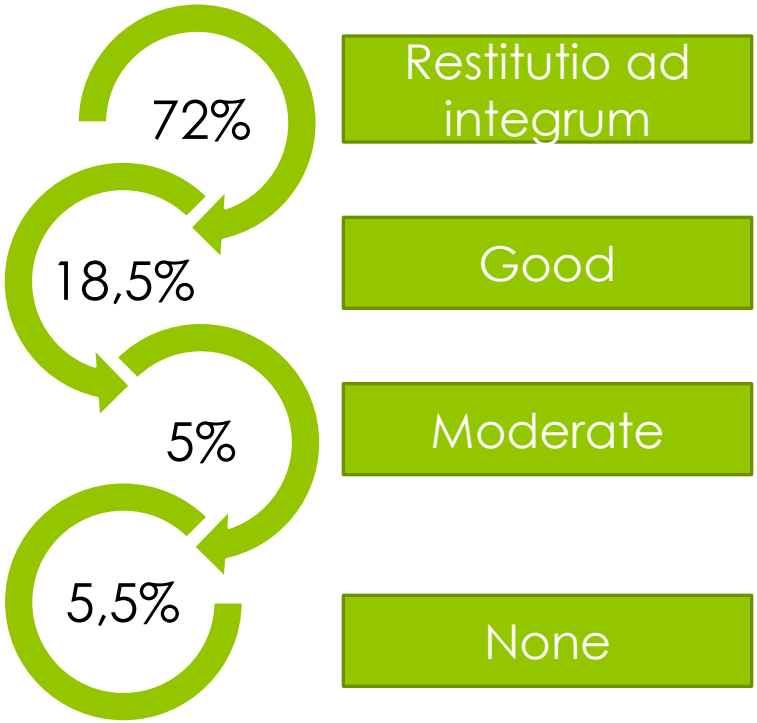
The above mentioned data, further to be useful for the classification of the pathology and its severity, are useful for collecting objective data from which to derive the statistical result of the research.
In particular, we identified 4 levels of achieved results that we explain below:

1. “Restitutio ad integrum”: the pathology is completely solved and the above mentioned symptoms disappeared;
2. Good: the vas scale of pain decreased significativaly and any other symptoms have been reduced
3. Moderate: at least one of the symptoms has been reduced
4. None: no improvements have been registered

Muscle and tendon disorders

Myotendinous disorders (Shoulder tendonitis and bursitis, Achille's tendonitis, Epicondylitis, Epitrocleitis)

298 patients



Images

Before

After

CRYO T-SHOCK could be used for reducing pain and improving movement capability for entering patient into a more complex rehabilitative process.

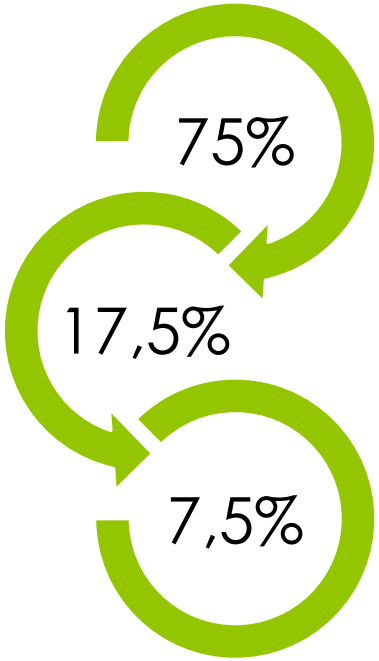
Application modalities

- Therapy: thermal shock
- Modality: manual massage
- Min. Temperature: from 2 to 6°C
- Max. Temperature: from 37 to 40°
- Application time: from 12 to 18 min.
- Sessions: from 6 to 10
- Frequency: daily

Pain relief

Painful pathologies
(back pain, talalgia, pubalgia, arthrosis pain)

172 patients

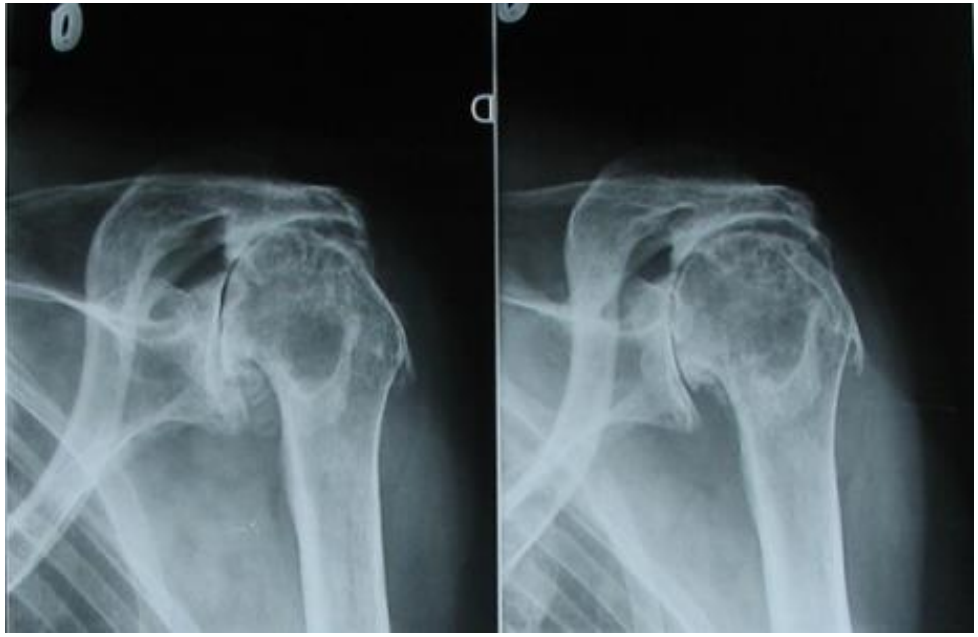


Restitutio ad integrum	129
Good	30
Moderate	13

Application modalities

- Therapy: thermal shock
- Modality: manual massage
- Min. temperature: from 2 to 6°C
- Max. Temperature: from 37 to 39°C
- Application time: from 8 to 16 min
- Sessions: from 4 to 8
- Frequency: daily

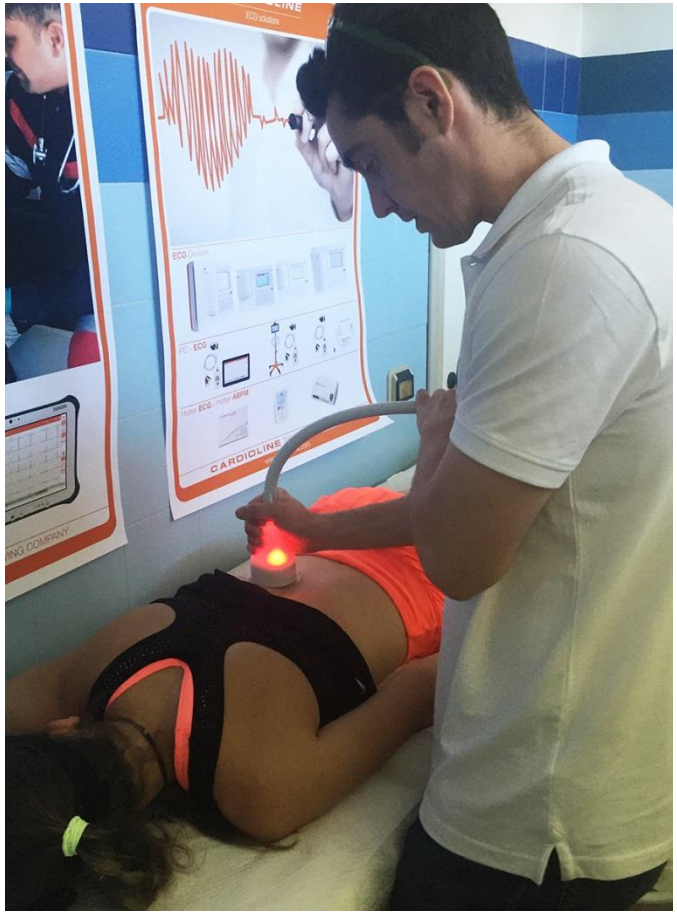
Images



Shoulder Arthrosis Before

After

Back pain treatment



During the treatment, physiotherapist performs a massage, made by quite slow rotatory movements. It is not needed to make any pressure over the patient’s body.

Traumas and post surgical

Edema and hematoma from trauma, contusions, sprains, elongations, and post-surgical (LCA, LCB)

106 patients

Restitutio ad integrum	77
Good	25
Moderate	4

Application modalities

- Therapy: cryotherapy*
- Modality. Manual massage
- Temperature: from 0 to 8 °C
- Application time: from 8 to 15 min
- Sessions: from 5 to 10
- Frequency: every two days

* In this opportunity, almost all Physiotherapy Centers belonging to the Pilot Group, were using cryotherapy only since the majority part of the treated diseases were on acute or pseudo-acute phase.

Images

Before

After

Distortion

Before

After

Treatment of LCA

Conclusions

First of all, no significant side effects or adverse events were reported from all collected applications. The procedure was well-tolerated, with 100% of respondents reporting a positive perception of treatment. Investigation results demonstrated more than 90% of positive results and patient's satisfaction.

Evidences are generally confirming the already well known benefits about applications of cold and hot over human body.

The advantage of CRYO T-SHOCK device is mainly made from technology which has been used for generating both cold and hot, from solid state technology, capable to deliver hot and cold, to keep almost monitored temperature modifications in real time, to generate fast exchange between cold and hot.

Conclusions

Therapeutic treatment with cold often proves to be the best first responder therapy in case of trauma. However, thanks to its multiple benefits is also used for numerous other applications.
Cold can also be applied in the period following an operation surgical.
Cryo thermal kinetics, made by altering heat and cold applications, can also bring benefits to those chronic processes with a high tendency to exacerbation, such as arthritis, degenerative joint diseases and tendonitis. Hot and cold, in these cases, can be effective especially when normal venous circulation is compromised, that is during the subacute or chronic phase of some traumatic and inflammatory conditions.

Conclusions

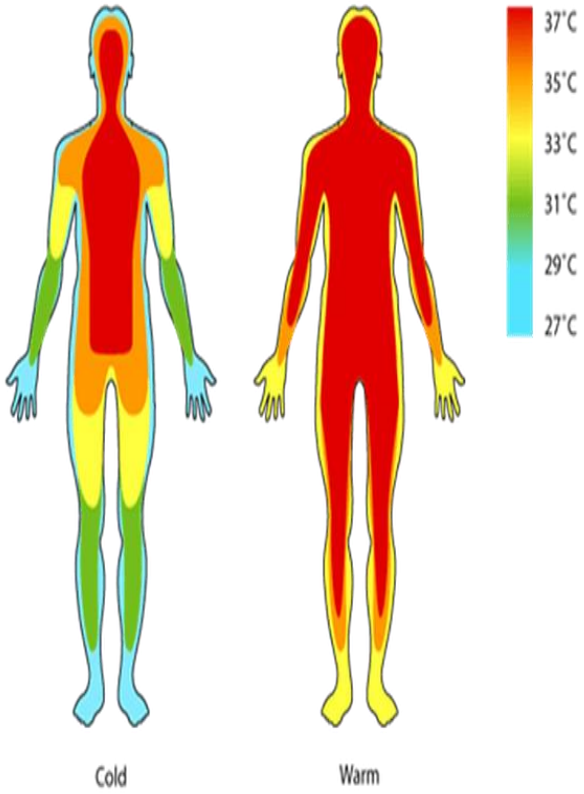
Alternate hot and cold (thermal shock), provoking vasodilatation and vasoconstriction, cause an increase in blood flow in the treated part. Pain relief occurs almost immediately (afterwards about half a minute) and offers the majority of patients immediate and rather lasting pain relief.
In addition, functional improvement of joints and general well-being may mature very quickly.
Thanks to strong temperature exchanges, microcirculation and connective tissue can also be stimulated.

The hyperthermic heating cycles followed by a resting phase, stimulate the opening - closing of the small vessels of the circle, optimizing the revascularization.

Conclusions

Well known in physiotherapy, the application of thermal shock takes its origins from the natural instinct to resort to cold or heat in emergency situations. “Miraculous water and gas” is famous on the sports: spray gas is commonly used as local anesthetic.

The human body is programmed to maintain homeostasis, functioning in equilibrium at the highest possible levels, this is physiology, alterations, unrequired imbalances lead to pathology with its evolution, healing is the return to physiology, to homeostasis and is carried out with different compensation mechanisms. Heat and cold are important environmental stressors and, as for everything, they should be read in "relative" form.



Conclusions

Also, increased mobility and freedom from pain after cryo thermal shock can be useful for introducing the patient into the rehabilitation exercises and rehabilitation.
In the long term, that is, after a series of treatments, the majority part of patients achieve a noticeable improvement in symptoms: more than 90% of patients report improvements in spontaneous and movement-related pain.
It is an effective medical treatment for various symptoms and diseases, as shown scientific literature on the subject. The treatment is based on the treatment of cold and, simplifying, is nothing but a powerful anti-inflammatory without side effects. It is easy to implement and safe if carried out locally by qualified personnel.

Conclusions

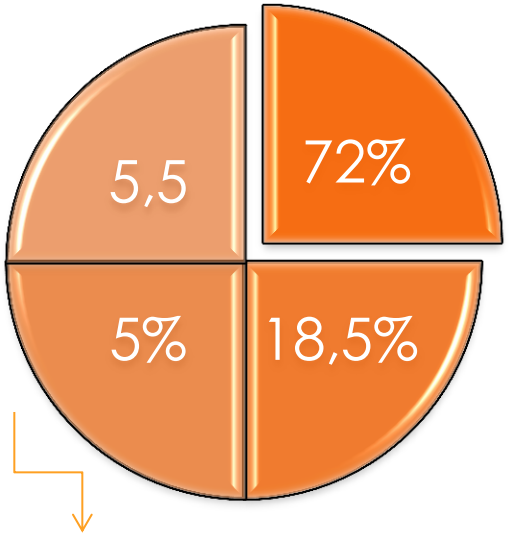
In sports medicine, Cryo T-SHOCK is an effective recovery modality for muscle and joint injuries by significantly alleviating inflammation after strenuous exercise and training by inducing a natural antiinflammatory effect.

“Achieving the optimal balance between strenuous training schedule and proper recovery is crucial in maximizing performance and gaining a competitive”

Decreased muscle soreness.
Accelerate muscle repair by an estimated 50%.
Decreased recovery time.
Quicker healing of post surgery or injury.
Increased blood circulation.
Boosted energy and Immune Syste

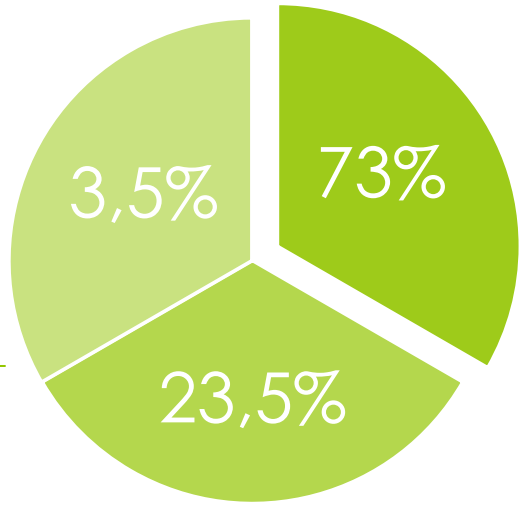
Conclusions

Muscle and tendon injuries



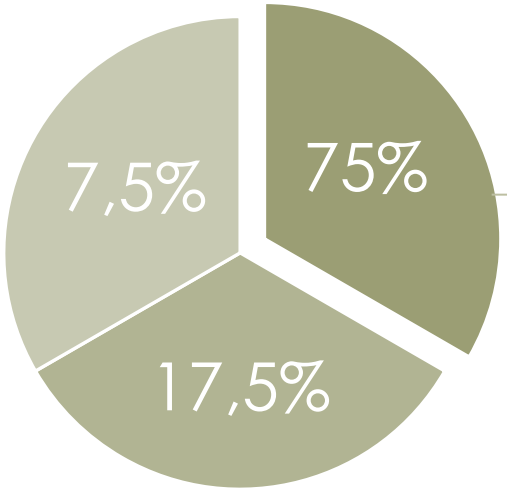
Very good and good results in 90,5% patients

Traumas and post surgical disorders



Very good and good results in 96,5% patients

Pain relief



Very good and good results in 92,5% patients

Conclusions

Cryo thermal shock therapy reduces pain and pro-inflammatory status, improves the quality of life of patients in a series of diseases, for several months from the end of treatment. It is a young method. The treatment spectrum is broad.
The indications vary a lot: from joint pain or back pain or pain in the spine from arthrosis or muscle stiffness, to inflammatory pathologies, to traumas or to muscle and tendon overload and then to a whole series of inflammatory pathologies, inflammatory and autoimmune. We From the background, the experience, the details coming from this clinical evidences, we could affirm that use of cryo thermal shock could be rapidly enlargeable to further medical fields and further diseases where cryo thermal shock could be applied without any special collateral effects and contraindications and effects could come very fast, from a very simple therapeutic approach.

Conclusions

We are referring to a form of energy coming from a technological system capable to control cold and hot, for being deeper and stable, assuring proper energy transfer. A controlled device capable to perform a successfully treatment without side effects.
Thermal shock modality may support the Physician and the Therapist in a more complex rehabilitative procedure where cryo thermal shock could take a very important place in terms, while it is supported and completed by the knowledge and capability of the operator.
Once the pain has been put down, the inflammation and the edema reduced, the therapist can intervene with all his professionalism and, depending on the case, use the manual and / or instrumental physiotherapy An ancient practice, that of the cold, if the same Hippocrates Father of medicine prescribed treatment with cold water for pain and inflammation.

Conclusions

After two millennia, it is curious to record - as did a review of the literature of 2007, published in Emergency Medicine Journal - that in fact 80% of doctors prescribe cryotherapy for the symptomatic treatment of traumas and soft tissue diseases . But it does so mostly based on experience (50% of cases) or common sense (30%) and only 17% of cases founding the choice on scientific reasoning.

Warning

For establishing application time, be care to take into consideration the main following matters:

Physical factors: which could have an influence over the thermal Exchange between applicator and tissue. In fact, while you set the desired temperature (cold or warm), usually, it takes time for reaching it. Also, consider that if temperature goes down or up and the temperature of the skin is decreasing or increasing, even if the temperature over the patient is not exactly the selected one,

the most important feedback is the patient's feeling. Sometimes, even if temperature is around 8/9 ° C, patient feel cold; if temperature is around 30° C patient could feel warm. On the above mentioned cases, consider that if you get 8/9° over the patient, it means that you were able to decrease temperature for around 11/12 ° C from the room temperature; and at around 30° C, it means that you were able to increase temperature for around 8/9 C° from the room temperature. So, the most important parameter is not the temperature you get from the unit, but the feedback of the patient who feels enough warm or cold. Warm or cold could be just a few or very hard, depending on the pathology and the objective of the treatment.

Warning

Patient’s factors: you must consider sensitivity and feedback of the patient, with reference to the body of the patient and to the volume of each treated part.
Factors coming from pathology: level of the pathology, level of pain, recovery process, interested area, desired result, etc.
Frequency of applications is varying with reference to the conditions of the pathology. Just after the trauma or just after a surgical operation, it could be also suggested to treat the part daily or maybe to
perform two treatments per day.
While a chronic inflammatory process is present, it could be possible to perform treatments daily during the first applications and passing to 2-3 applications per week on the next phase up to the pain relief and inflammations left.

Warning

Contraindications

- Pregnancy
- Tumors
- Ipersensitivity to cold and/or warm
- Recent Wounds
- Diabetes

Collateral effects

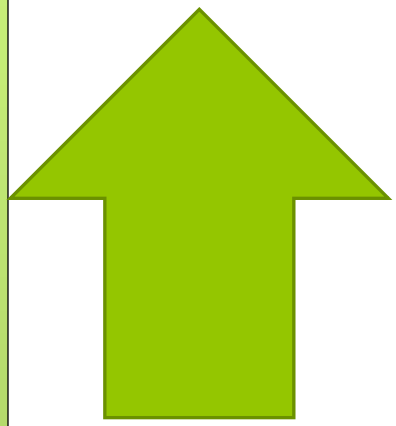
- Temperature skin reactions

Warning

It is advisable that, in a situation where the effectiveness or otherwise of a therapy depends to a large extent on the sensitivity of the physiotherapist who leads it, the clinical results are strongly contradictory.
In this regard, we recommend:

- use the machine preferably after following the appropriate training;
- exclude any contraindications, inform the patient about the objectives that can be pursued and the sensations that he may experience during therapy and subsequently.

Advantages



- Manually made
- Very simple to perform
- Short appliacation time
- Visible benefits into the first application/s
- Useful also over acute phase
- Few contraindications
- No collateral effects
- No gas, no vacuum, no pressure to be used
- Low cost of maintenance

Clinical evidences

Principles about effects in Aesthetic disorders

From a wide International bibliography and evidences, we learn about positive effects of cryo therapy and diathermy in stimulating collagen, reducing inflammation and water retention inflammation when apply to cellulite disorder.

What is Cellulite?

Cellulite is the changes in skin texture that result in an "orange peel" appearance to the skin. Cellulite is much more common in women. Studies show 85-98% of women have some cellulite. Men and women organize their fat differently. In men, the connective tissue fibers that organize and support fat run primarily parallel to the skin. This means that men have minimal pulling down of the skin by fat deposits, and therefore smoother skin. Unfortunately for women, their fat is organized perpendicular to the skin. This results in a pulling down of the skin by the connective tissue support structure and an uneven surface.

Principles about effects in Aesthetic disorders

Cellulite is a normal process in women. Only in the last few years have any studies been done to identify the cause of cellulite. Effective treatments are an even more recent development. Cellulite forms in the superficial fat. All fat is not cellulite, only the part present in this superficial layer. The superficial layer is the last area to be affected by weight loss.

Therefore, exercise and weight loss do not eliminate cellulite.

Even women who exercise regularly and follow low-fat, nutritious diets may still have cellulite. **This makes weight management and cellulite treatment completely different issues.**

The first cause of cellulite is a hardening of the connective tissue support system of fat. These are referred to as connective tissue (fibrous) septae. These are made of collagen.

Over time, these septae harden and contract. The contraction results in most of the dimpled appearance that characterizes cellulite. Additionally, the contraction leads to a blockage of the blood vessels and lymphatics. The blood vessel blockage further hardens the septae. The lymphatic blockage leads to thick, swollen appearing skin.

Principles about effects in Aesthetic disorders

The second major cause of cellulite is protrusion of fat cells into the lower part of the skin known as the “reticular dermis”. This protrusion results in worsening of the dimpling.

Treatments for cellulite need to address both of these issues in order to have really good results. Until recently, no treatments were available to address either issue effectively, much less both.

Who suffers from cellulite?

Cellulite is a problem that primarily affects women; even women who are not overweight and who keep fit and healthy suffer from it. Although obesity does not cause dimpling, it does become more obvious with weight gain. More than 80 percent of women have some degree of cellulite.

Where does cellulite most commonly occur?

The accumulation of lipids in the fat cells most commonly occurs on legs, buttocks, abdomen and arms.

Principles about effects in Aesthetic disorders

Special effects of cryo thermal shock over cellulite:

Metabolic: it is made by the increasing of membrane permeability which make easier metabolic exchanges, by accelerating metabolism and calories consumption.

Circulatory: warm which is coming from hyperemia that mechanical action is capable to generate inside the human body, by improving blood flow.

Fibrolitic: “micro-massage” treatment is capable to destroy fibrotic tissue. This is made from the action of cold and warm and the relevant fast exchanges.

Hardening: this is due to the response of human body to induced external temperature which stimulates a whole reaction of all cellular layers, from skin to blood flow, from muscles to tendons. It is a very hard stimulation of connective tissue and collagen and this stimulation grants a good aesthetic improvement of skin and elasticity.

Principles about effects in Aesthetic disorders

The use in fat removal refers to the studies conducted by some US researchers who have found that the lowering of the temperature at the level of fat cells until they reach about 12-14 ° C, it involves the necrotization "(a kind of so-called "cell death" and "apoptosis"). The fat cells thus necrotized, thanks to the physiological and / or induced drainage processes (using manual and / or instrumental methods, such as tecartherapy, or pressotherapy, etc.), are naturally evacuated.

The method actually allows to reduce local fat cells (into the part of the body where the treatment has been performed). The reformation of fat in those areas depends on the patient's subjective conditions, his metabolism, his dietary behavior, and movement. Therefore, in short, the method is definitive within the limits of the restoration of the physiological, dietary and behavioral conditions of the treated patient.

Principles about effects in Aesthetic disorders

From the above mentioned evidences we get from the International bibliography and references, we would like to investigate about the following MAIN INDICATIONS OF CRYO T SHOCK IN AESTHETICS:

- CELLULITE / PEFS VASCULAR ALTERATIONS
- WATER RETENTION
- REMOVAL OF UNDESIRED FAT
- BODY AND FACIAL CUTANEOUS AGING
- IMPROVEMENT OF MICROCIRCULAR
- POST SURGICAL INTERVENTION EDEMA

Principles about effects in Aesthetic disorders

Smashing and melting of hardened connective tissue with the consequent metabolic block of subcutaneous fat does not occur through the administration of medicines, but thanks to the natuarl energy and micro-massage, which concentrates on the first 2/4 cm of depth, where cellulite and fat is located;

- the elimination of liquids in excess and metabolic wastes occurs through a natural re-absorption of the lymphatic system;
- cold and warm cause an increase of hyperemia and skin permeability;
- this treatment is not invasive and the patient does not feel any pain.

Principles about effects in Aesthetic disorders

The new treatment of fat mass and cellulite

The problem is not cellulite or fat, but excess fat (hence the name of lipodystrophy).
This is the reason for the female desire for a reduction in volume, the operator must always cope with a clinical evaluation, assigned to examine the conditions of excess in fat.

To treat in a targeted but non-invasive way the water retention and the accumulation of localized cellulitis of the legs or the swelling that hits from the ankles up, then the calves, thighs, and buttocks can be resorted to cryotherapy. "Crio" comes from the Greek "cold", this therapy is based on this principle: the cold makes the body molecules tighten and when you emerge from a low temperature the same ones expand again increasing the blood flow; this relieves pain, swelling and inflammation.

Pilot Group

The group of patients are women and men, from 18 to 65 years old and for each of them, the following personal and anamnestic data have been collected:

- Sex
- Age
- Weight
- BMI
- Body part to be treated and relevant volume in cm
- Pathology
- Symptoms: pain, swelling, edema, heat, redness

The above mentioned data, further to be useful for the classification of the pathology and its severity, are useful for defining at first the aim of the treatment and collecting data at end of the whole session.

Pilot Group

From the statistic point of view, we identified 4 levels of achieved results that we explain below:

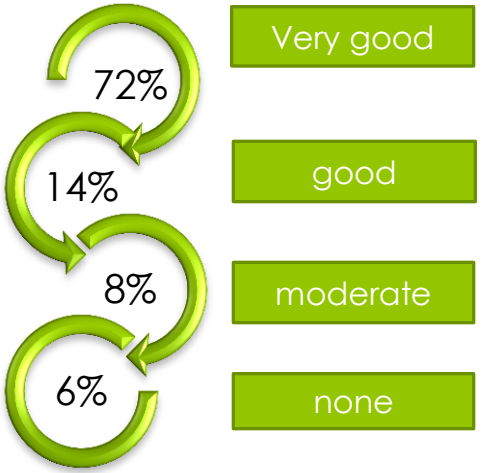
1. Very good: the pathology is completely resolved, the above mentioned symptoms disappeared, BMI and/or volume significantly reduced;
2. Good: almost all the above symptoms disappeared, pathology, BMI and or/volume have been reduced;
3. Moderate: at least one of the symptoms has been reduced, just a few improvement in BMI and/or volume
4. None: no significant improvements have been registered

Evidences

Details coming from the Pilot Group

Evidences

Fibrotic and Sclerotic Cellulite (gluteus and legs)

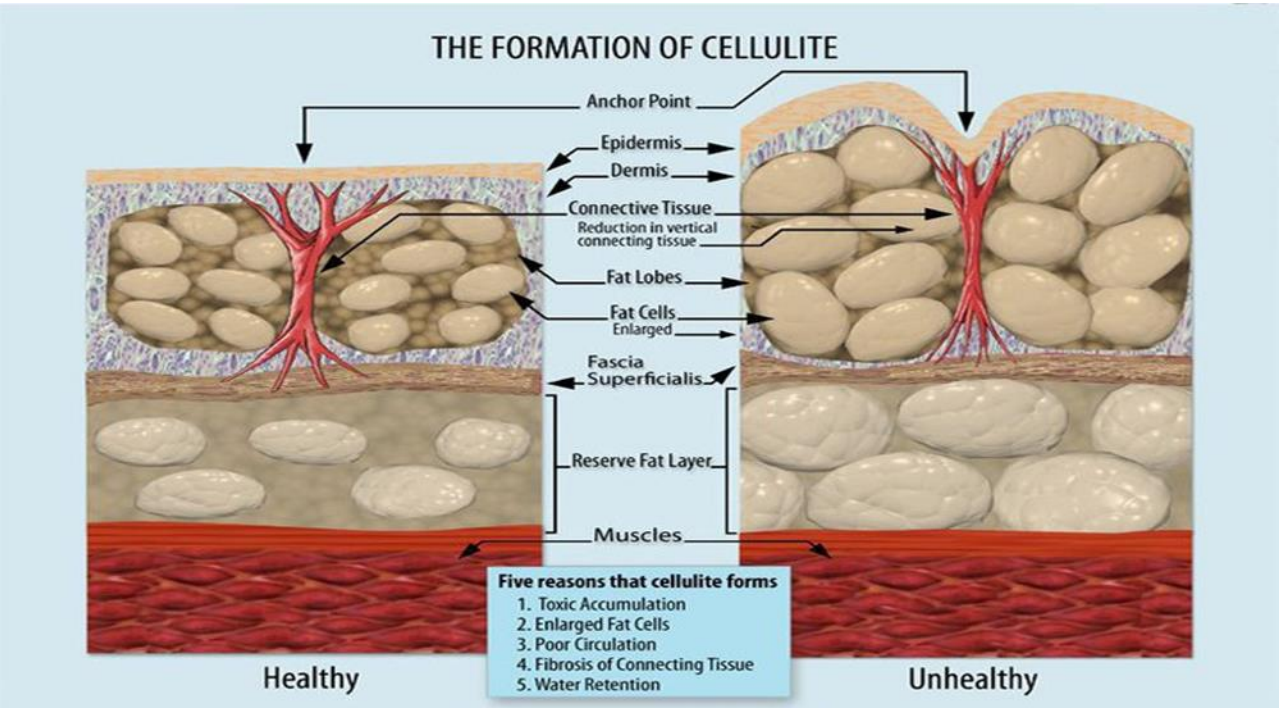


375 women

24 to 62 years old

- 270 very good (significant BMI and volume reduction, symptoms regression)
- 52 good (regression in inflammation, improvement in skin aspect, volume and/or BMI reduction)
- 31 moderate(small improvement in inflammation and skin aspect)
- 22 none (any improvement)

Cellulite disorders



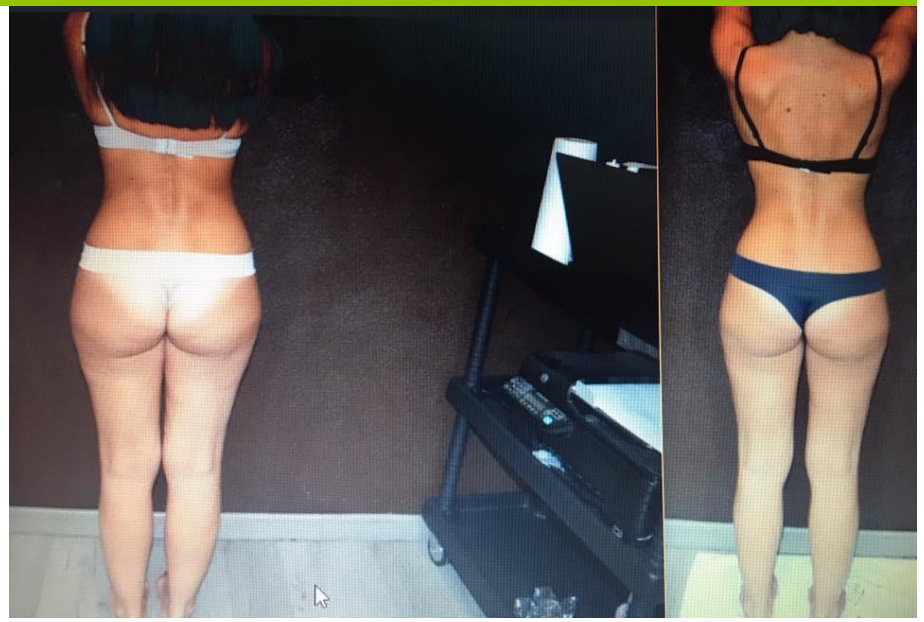
Layout of damaged layers

Visible aspect of cellulite

Cellulite disorders




Cellulite improvements: both visible and by scintigrify



Cellulite disorders

Before

After

Application modalities

- Therapy: thermal shock
- Modality: manual massage
- Min. temperature: from – 4 to 6°C
- Max temperature: from 36 to 39°C
- Application time: from 20 to 30 min
- Sessions: from 8 to 12
- Frequency: Twice a week

Conclusions

The study aimed to observe the effects of the new technique in the treatment of cellulite. Cellulite represents an important social problem.

The findings show that the action of Thermal shock is a safe, effective, and well-tolerated noninvasive treatment.

The goal of this treatment is to decrease cell growth and reproduction (cellular metabolism), increase cell survival, and reduce inflammation, decrease pain and spasm, promote constriction of blood vessels (vasoconstriction), and when using extreme temperatures, destroy cells by crystallizing the cytoplasm, which is the liquid that is inside the cells, also known as intracellular fluid.

From the Pilot Group, we may affirm that CRYO T-SHOCK is a useful and effective technology in reducing cellulite. The process may stimulates connective tissue in specifically affected areas of the body, improving appearance by manipulating the connective tissue itself. Increased elasticity is achieved by activating the organic process of the body, developing the connective tissue.

Conclusions

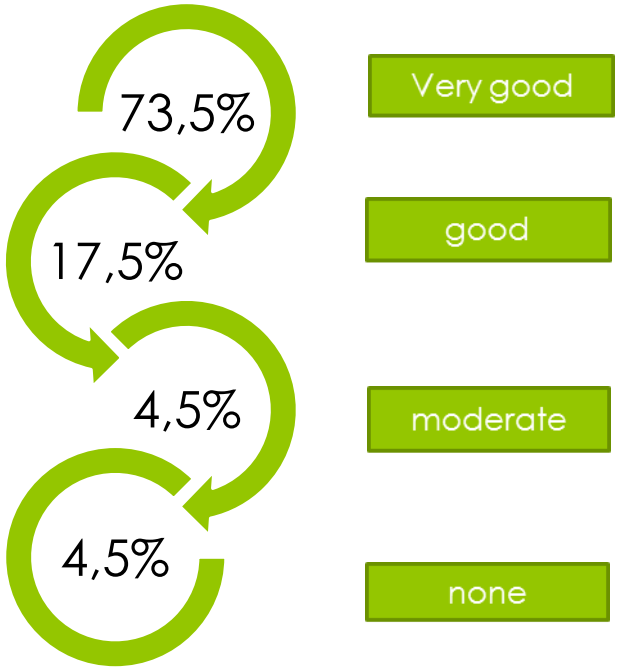
An anti-inflammatory response is produced capable to release healing mediators, and the creation of newly thickened bands of collagen being deposited into the skin.
COLD and HOT have been used over the years to help patients with pain associated with poor circulation and stiff joints. This process has been adapted to improve the appearance of the skin.
CRYO T-SHOCK is effective in few days.

Treatment of Cellulite (over the different phases of Cellulite) is generally performed by assuring a shock in terms of temperature. We preferred to increase skin temperature by using warming side of CRYO T-SHOCK and cooling immediately after for provoking a great shock.
The latest part of treatment has bee done for helping drainage of liquid retention and fat.

Fat removal

Undesired fat removal (gluteus, legs, arms, stomach)

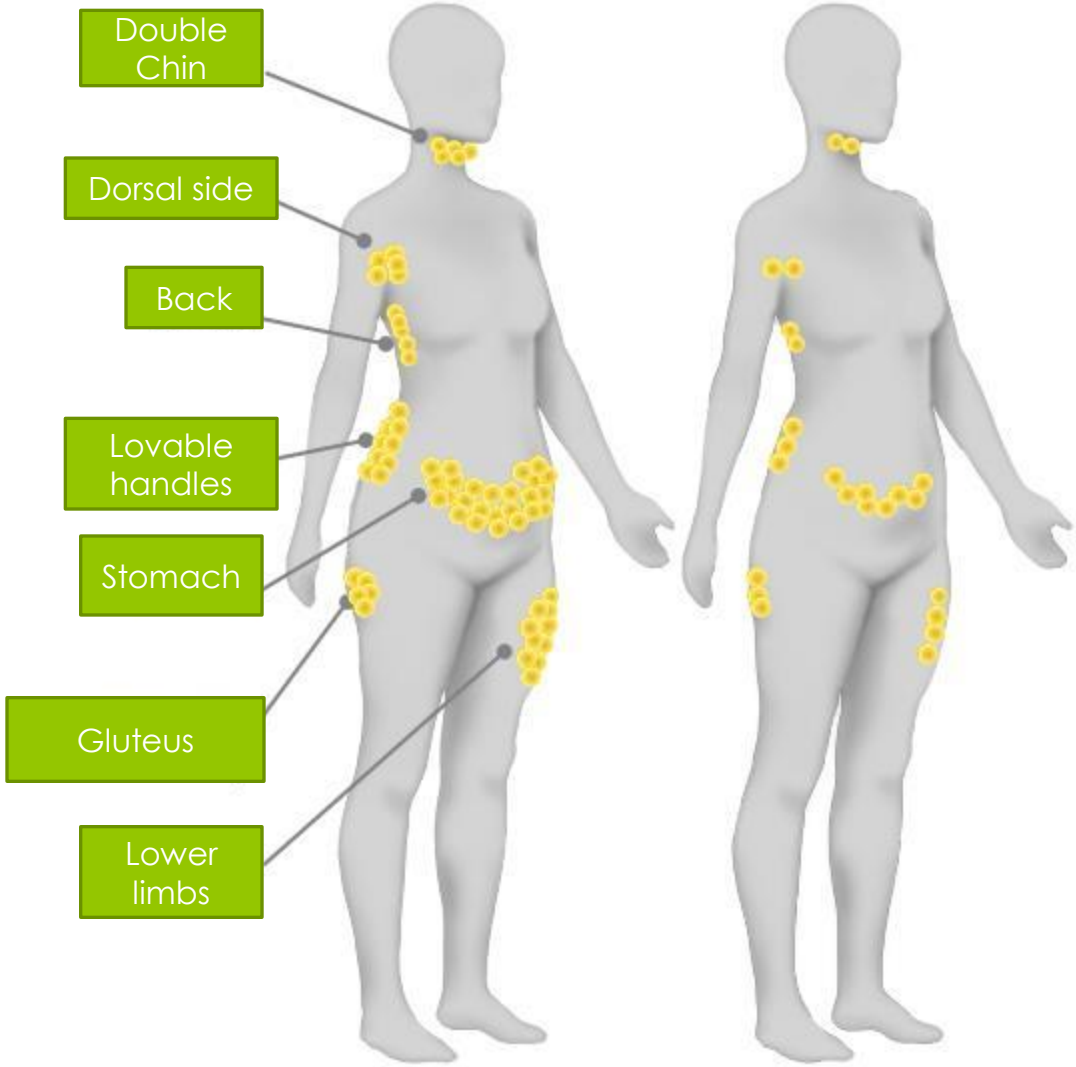
340 Women and men



18 to 65 years old

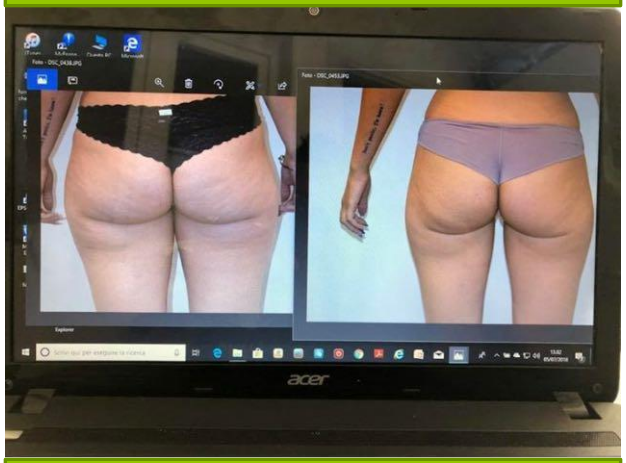
- 250 very good (whole resolution, BMI/ volume reduction)
- 60 good (improvement in skin aspect and BMI/volume reduction)
- 15 moderate(small improvement in inflammation and skin aspect)
- 15 none (any improvement)

Areas to be treated



Images

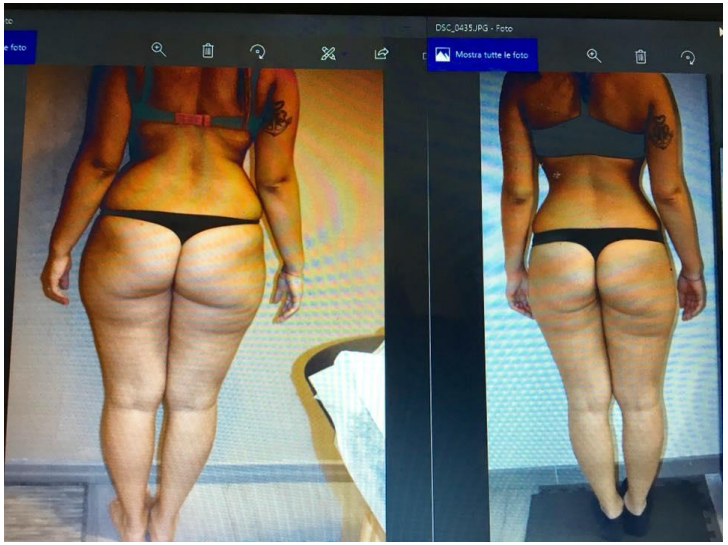
Gluteus
Before and after



Legs
Before and after

Images

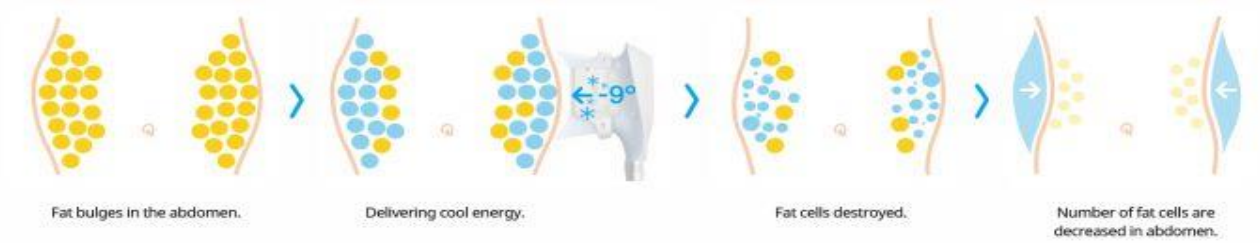
Massage treatment must be slow, sometimes push over the fold for concentraing enetrgy action.

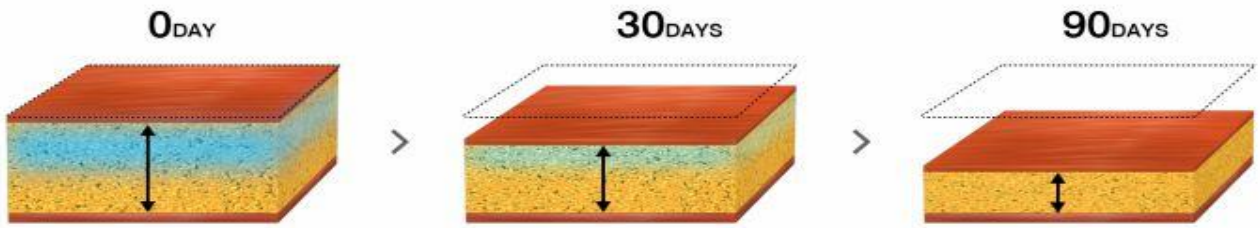


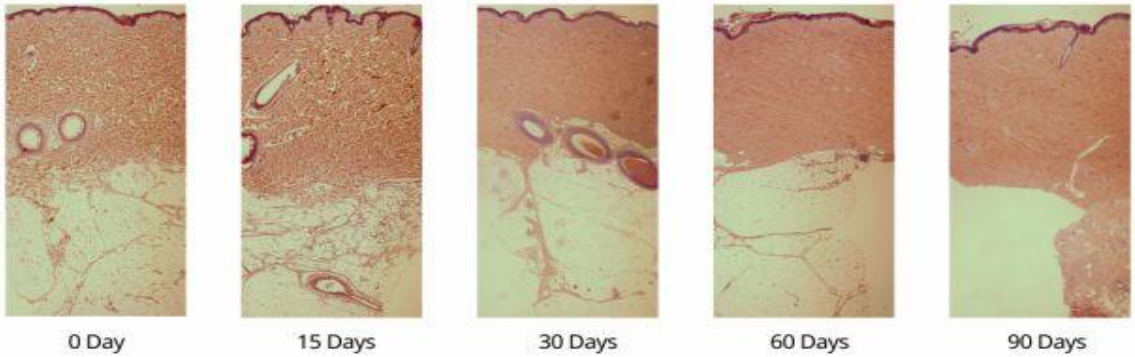

1
15/11/17
2
21/11/17
PICCOLLAGE
27/12/17
3
24/1/18
5
PIC•COLLAGE


1
2
3
5
PIC•COLLAGE

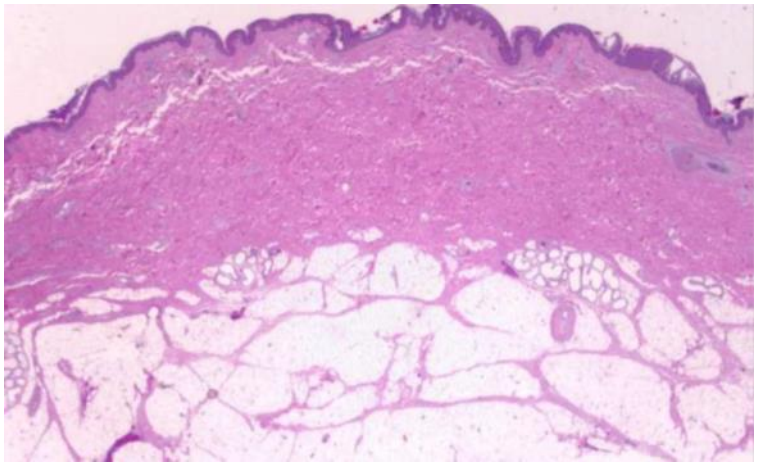
Apoptosis process

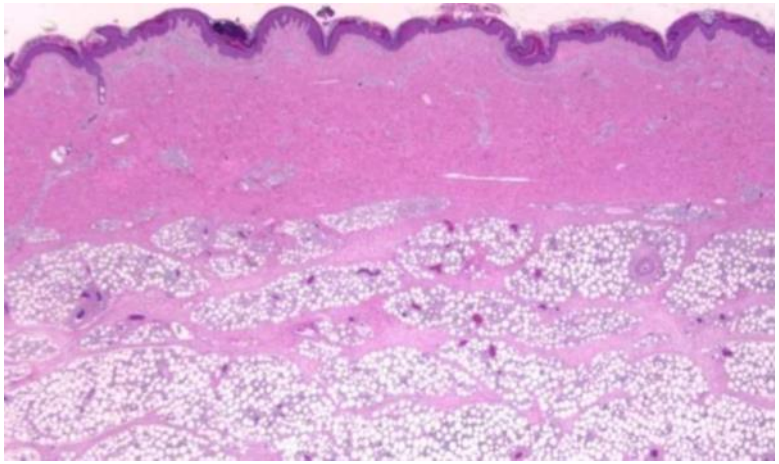


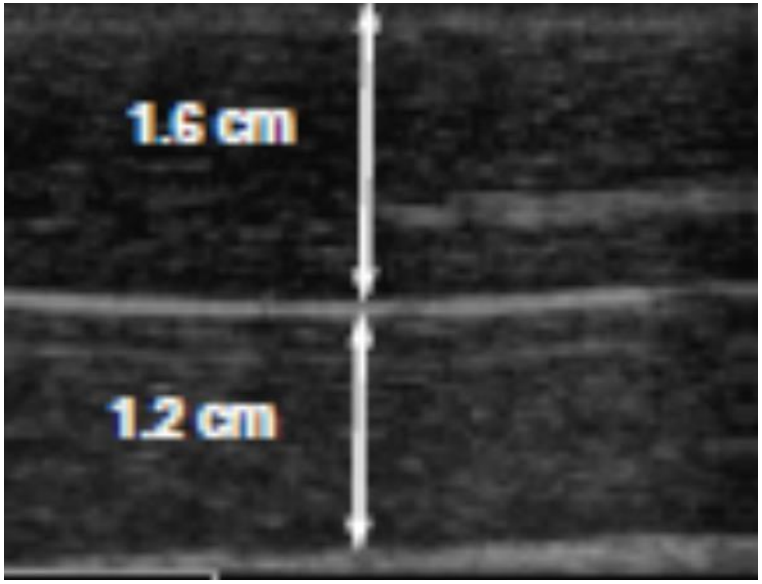


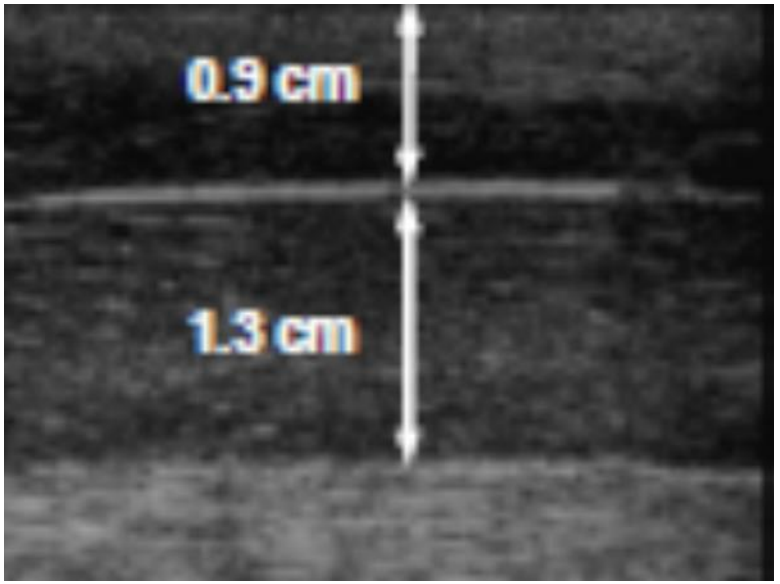


Reported images









Application modalities

- Therapy: cryotherapy*
- Modality: manual massage
- Temperature: from – 8 to 4 °C
- Application time: from 20 to 40 min
- Sessions: from 4 to 12
- Frequency: once a week

*With reference to the existing international bibliography and evidences, study has been done by using cryotherapy only for being adherent and comparable to the common knowledge.

Conclusions

Cryotherapy is a contemporary method of reducing fat by controlled extraction of heat from adipocytes. It is a safe, well-tolerated, and effective noninvasive fat removal methodology.
Cryotherapy reduces fatty deposits by using extreme cold to constrict the blood vessels. Noninvasive cryolipolysis results in a predictable and noticeable fat reduction within 3 to 6 months and does not cause skin damage.
It is a non-invasive treatment of adipose tissue to induce lipolysis - the breaking down of fat cells:
- to reduce body fat without damage to other tissues. It consists of a special developed technique where warm and cold are used and applied directly to the patient's skin Subcutaneous fat cells are naturally more vulnerable to the effects of cold than other surrounding tissue.

Conclusions

Exposure to cooling causes fat cell apoptosis - a natural, controlled cell death, which leads to the release of cytokines and other inflammatory mediators that gradually eliminate the affected cells. Inflammatory cells gradually digest the affected fat cells in the months after the procedure, reducing the thickness of the fat layer. Lipids from the fat cells are slowly released and transported by the lymphatic system to be processed and eliminated
Temperatures that are beneath freezing will trigger the fluids that bind fat cells together to crystallize. This crystallization really destroys the cells and the bonds holding the deposits together. Repeated remedies will slowly take away upper ranges of fat. The cells which have been destroyed are pulled into the blood stream after which disposed of by means of the lymphatic system
Cryotherapy makes your metabolism work three times faster and reduces cellulite. The sub-zero temperatures make your blood circulation soar, boosting oxygen and nutrients around the body, speeding up removal of toxins and even toning your muscles. After three sessions – that’s like, nine minutes in total –your cellulite will be reduced and you’ll be burning fat faster. Cryotherapy should be used as part of a healthy living plan

Conclusions

CRYO T-SHOCK is an incredible fat-reducing treatment that melts away excess fat, allowing to contour r body curves and lose inches fast. This non-invasive body treatment achieves visible results by freezing and breaking down fat cells located deep under the skin to decrease the amount of fat volume in the targeted area.

CRYO T-SHOCK is a non-invasive procedure that can be used all over the body where excess fat tends to accumulate. For defined curves and a sexy, streamlined shape, CRYO T-SHOCK is a safe and effective treatment that can also be used in tangent with other treatments to maximize inch loss.

Conclusions

The main goal of our activity was to improve aesthetics of skin, increasing elasticity and atrophy of the different tissues; reducing edema and liquid retention which the patient could feel like pain and tiring.
Fat removal was one of our main goals and, despite our doubts into the benefit of this new modality, results were higher than expected. Volume of all treated people has been reduced and effects were visible just from the first sessions.

The special technique used into the treatment of cellulite includes vertical micro-massage and horizontal micro-massage.

Conclusions

The hand-piece of CRYO T-SHOCK, is passed on well-defined areas to concentrate the effect and optimize the time, a neutral gel is applied to allow the handpiece to slide.
It is advisable to perform manual massage by following the lymphatic discharge routes.

Application time varies depending on the imperfection and the area to be treated as the temperature to be used.
It is also useful to apply CRYO T-SHOCK in the treatment of the adipose and edemo-fibrous panniculus, reactivates and improves the microcirculation, leading to an increase in cellular metabolism with excellent results.

Warning

Suggestions

Select an area of the body of the patient which is not so vast

Make sure you execute a slow massage over the selected area of the body.

The best results come while the treatment is made on the skinfold

To improve benefits and results of the treatment, it is advisable to suggest to the patient to perform, by the next few days from each application, drainage over the treated area to help fat elimination by the physiological process.

Evidences

Body and facial toning

Backgraound

- From the existing evidences, we learn that CRYO THERMAL SHOCK is capable to increase endocellular metaboslim. Metabolism stimulation could provoke the following natural reactions of human cellular layers:
-
- smoothing: restore the endocelluar organic turnover
- detoxification: increases oxygenation and tissutal nutrition
- brightness: revitalizes metabolic activities of every single cell
- turgore: increases hydratation of surface layers enriching the skin thickness
- fiber distention: connectively and elastic fiber are recommended

Pilot Group

The group of patients are women and men, from 24 to 65 years old and for each of them, the following personal and anamnestic data have been collected:
Sex
Age
Visible signs: wrinkles, signs of aging, low brightness of the skin, compromised skin and muscle toning

From the statistic point of view, we identified 4 levels of achieved results that we explain below:

1. Very good: all above visible signs completely disappeared;
2. Good: almost all the above signs disappeared;
3. Moderate: at least one of the signs has been disappeared or at least reduced
4. None: no visible effects

Backgraound

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-
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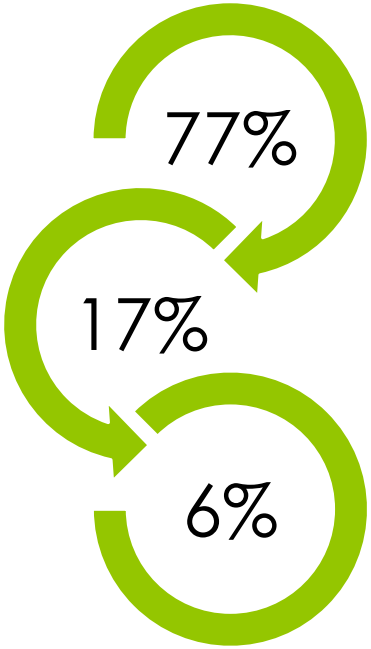
- fiber distention: connectively and elastic fiber are recommended

Anti-aging facial lift

Wrinkles, improving elasticity, brightness, toning

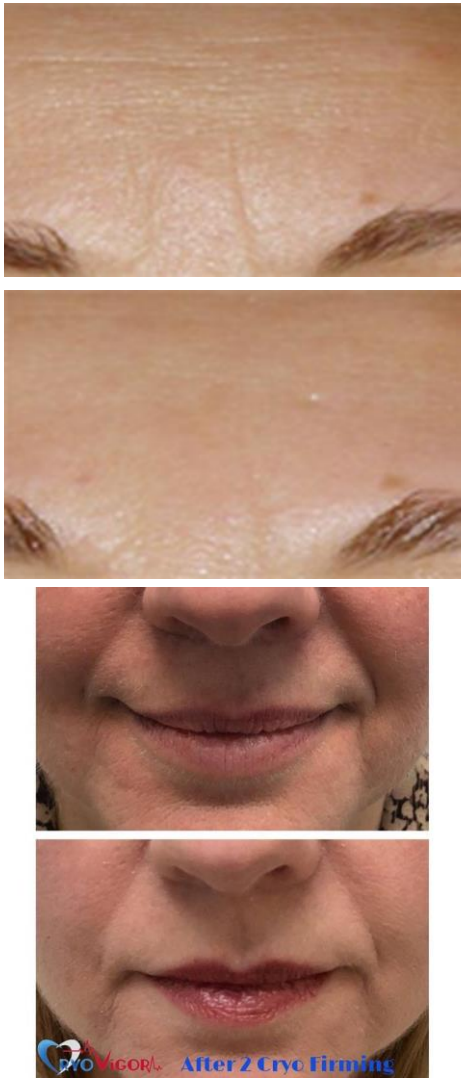
235 patients



Very good	181
Good	40
Moderate	14

Images


Prima
Prima
Dopo
PIC•COLLAGE
Dopo
PIC•COLLAGE


After 2 Cryo Firming

Images

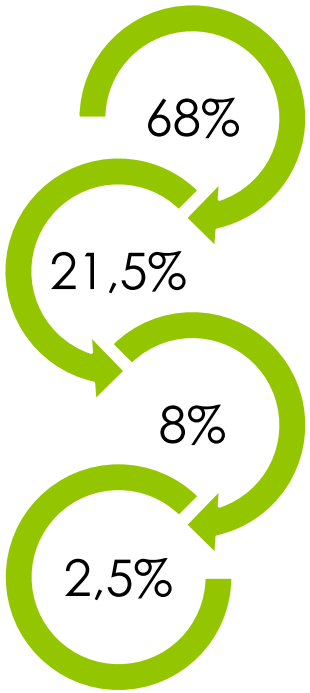
Application modalities

- Therapy: theraml shock
- Modality: manual massage
- Temperature: from 0 to 8 °C
- Max. temperature: from 37 to 40°C
- Application time: from 12 to 16 min (each side)
- Sessions: from 3 to 8
- Frequency: twice a week

Body toning

Compromised skin and / or muscle body tone

112 patients



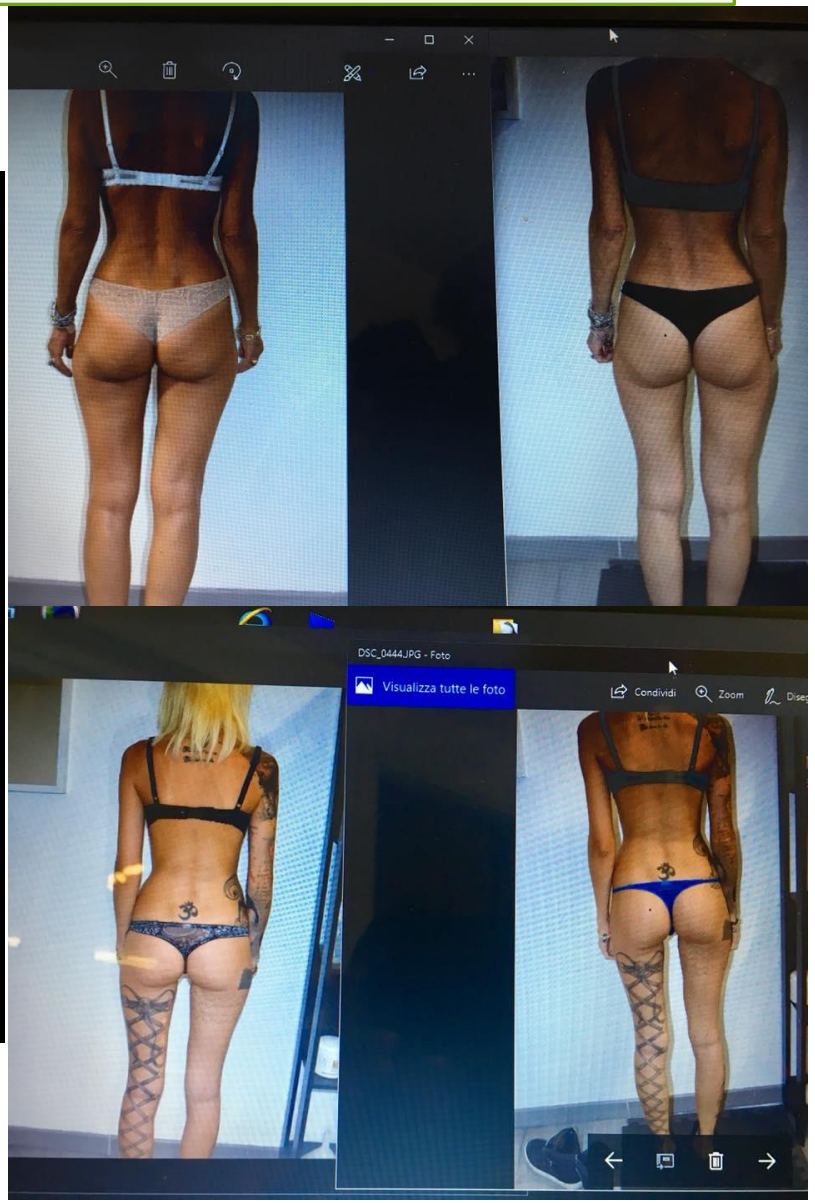
76	Very good
24	Good
9	Moderate
3	None

Images

After | Before

Before | After

Images



Images

Application modalities

- Therapy: thermal shock
- Modality: massage
- Min temperature: - 2°C
- Max. temperature: 40°C
- Application time: 15 to 20 min
- Sessions: 4 to 10
- Frequency: 2-3 times per week

Conclusions

Body shaping and facial toning

Cryo thermal shock has been proven to be a very safe method for body toning, and is accomplished with only minimal discomfort. Expected side effects are temporary erythema, bruising, and transient numbness that usually resolve within 14 days after treatment.

Cryo thermal shock improves the general condition of the skin by increasing oxygen and nutrient supply to the skin.

Cryo thermal shock tightens the skin and prevents wrinkles.

Generally, more positive results in toning and resolution of visible symptoms were concerning face lift. We assumed that this is why facial muscles are concentrated in a very small area and could be widely treated.

From the collected data and the above mentioned images, we may notice also may notice that positive results including “very good” and “good” are near to 90%, even if we may record less than 70% of whole satisfaction.

Conclusions

During Cryo thermal shock treatment the skin vessels and capillaries undergo a period of vasoconstriction (constriction of blood vessels) followed by vasodilatation (dilation of blood vessels) upon finishing the session. This causes toxins stored in the layers of the skin to be broken down and flushed away. The intense cold activates collagen production in the deeper layers of the skin, leaving your skin firm and tight. After several applications, clients have noticed the skin becoming smoother and more even toned with regained elasticity and improved overall “youthful” feeling.

This treatment is around 20-30 minutes in length. Again we will focus on one area at a time but we can perform more than one area in a session. The device causes local metabolism and microcirculation to improve in the area we are focusing on, with both these components improving this will boost your production of collagen eliminating cellulite, toning the area and reducing the signs of aging.

Conclusions

Provoking a shock by cooling and or shocking (alternating cold and warm) the skin with Cryotherapy around the face and neck, triggers deep layers of collagen into production.
This will smooth out facial lines, reduce blemishes, wrinkles and makes tighter appearance within few minutes. A full set of applications (from 4 to 8) will naturally begin to renew production of collagen. Consequently, the result of a course of treatments is a long lasting return of a more youthful, clear and youngest skin.
- Appearance of wrinkles and fine lines shall be highly reduced.
· Production of collagen resulting in fuller, more youthful and beautiful rejuvenated skin.
- Puffiness around the eyes shall be significantly reduced or totally eliminated.
· Pores on the face and neck shall be reduced in size, limiting the intake of toxins, dirt and grime.
- Benefits over lymphatic system, flushing away built up toxins, soothe inflammation and irritation, removing puffiness, and redness.
After one session you can clearly see the reduction of lines, puffiness and clearing of skin color.

Conclusions

Cryo t-shock face-Lifts safely performed with high benefits and without any special collateral effects and contra-contraindications by using not so hard temperature for respecting comfort of each patient without any limit into the age.

The Cryo T-SHOCK Toning Facial is a relaxing, non-invasive treatment using a controlled temperature on the face and neck. The treatment boosts blood flow areas accelerating collagen production and releasing toxins. The collagen decreases pore size and wrinkles resulting in a clearer, smoother and tighter appearance. Repeated facial sessions will increase the natural production of collagen, a protein which allows the skin to be more elastic overtime, reducing and even eliminating wrinkles and other blemishes. The increased blood flow also reduces toxins, inflammation and puffiness in the face and eyes.

Upon completion, users immediately report their skin feeling tighter and smoother.

The Cryo Toning Facial could be also effective on eczema, psoriasis, rosacea, scarring and other inflammatory skin issues.

Warning

Contraindications

- Pregnancy
- Tumors
- Ipersensitivity to cold and/or warm
- Recent Wounds
- Diabetes

Collateral effects

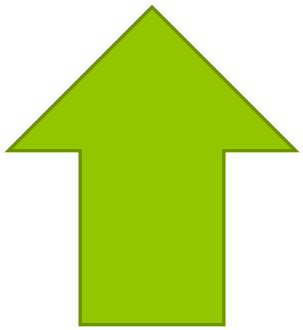
- Temperature skin reactions

Warning

It is advisable that, in a situation where the effectiveness or otherwise of a therapy depends to a large extent on the sensitivity of the operator who leads it, the results could be strongly contradictory.
In this regard, we recommend:

- use the machine preferably after following the appropriate training;
- exclude any contraindications;
- inform the Client about the suitable objectives that can be pursued and the sensations that he may experience during therapy and subsequently.

Adavantages



- Manually made
- Doesn't apply vacuum, gas, pressure
- Simple to perform
- Visible benefits in few applications
- Large spectrum of applications
- Few contraindications
- Few collaterale effects
- Cheap device
- Low cost of maintenance

Guidelines

Before CRYO T-SHOCK, it is advisable to collect some information about Client's skin and sensitivity:
- temperature (cold and hot) sensitivity of the skin, especially concerning the most delicate and exposed parts, such as face, hands and décolleté;
- all possible allergies: food, topical, respiratory;
- hypersensitivity to cold and / or heat. Ask if the Client gets any reaction/alteration in winter time over hands, facial skin or other parts of the body.

Pay attention in doing CRYO T-SHOCK to people with any kind of hypersensitivity and / or allergies.

In using CRYO T-SHOCK, a first "soft" approach is recommended, avoid very low (not less than 6 / 8 ° C) or very high (not more than 36 and 37 ° C). Increase or decrease the temperature starting from the second session and use the first session as a "first feedback" about Client's reaction to CRYO T-SHOCK.

If possible, apply without making CRYO T-SHOCK, just a few of cryo gel on the part of the body to be treated to verify its reaction.

Guidelines

During CRYO T-SHOCK, the sensitivity of the skin is explained by two phenomena:

• First of all, the skin's barrier function is reduced: the epidermis imperfectly plays its role as a protective shield against environmental aggressions. Potentially irritating agents can thus penetrate deeper and trigger inflammatory reactions. Likewise, water losses from the epidermis increase and the skin dehydrates more easily.

• In addition, the skin tolerance threshold becomes lower. To any aggression, even minimal, an abnormal quantity of inflammation messenger molecules (cytokines) is produced. This skin sensitivity can be linked to genetic, but also psychological factors: skin is the mirror of our emotions and an inner malady can result in hyper-reactivity. The skin can become sensitive also due to external factors: excessive use of aggressive cosmetic products, excessive exposure to the sun, peeling or laser sessions, contact with external materials (such as cream, gel, metal).

Guidelines

Sensitive skin reacts exaggerated when exposed to some normally well-tolerated factors: heat, cold, calcareous water, spicy foods, application of cosmetic products or even strong emotions.
The skin sensitivity manifests first of all on the face and sometimes on the neck and rarely extends to other parts of the body. Some skins are sensitive in nature and remain for life. However, their reactivity tends to lessen with age, particularly after menopause in women. Other skins have only periods of sensitivity, for example in winter: the cold and dry air of heated interiors can trigger a reactivity that naturally fades with the return of good weather.