

Cryolipolysis with active vacuum technology and simultaneous stimulation of the microcirculation in body reharmonization: comparative study on 40 patients divided into 2 cohorts

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Abstract

Background: cellulite is a common syndrome. Many studies have examined whether cellulitis should even be considered a disease. The nature of cellulite is linked to different physical and hormonal factors as well as to lifestyle and is characterized by the presence of localized adiposity and weight increase.

Aim: we aimed to measure the clinical and scientific value of cryolipolysis treatment combined with bioactive currents. We studied both the effectiveness of cryogenesis on adipose tissue and the action of 50-Hz current pulses on tonicity.

Methods: enrolled patients were evaluated with an anthropo-plicometric examination, ultrasonography, blood tests, and photographs and divided into two groups: one group maintained a low-calorie balanced diet and the other group combined the same diet with cryolipolysis treatment. The cryolipolysis device used in the study had an active no-inertial vacuum technology for the maintenance and integrity of the vascular system, suffering if subjected to cryogenesis and aspiration. Bioactive currents preserved the functionality of the cells and tissue oxygenation. Results were obtained at baseline and at 8 weeks after treatment delivery. We call this specific device cryoliposculpt.

Results: we enrolled 40 patients (mean age, 43 years), 20 patients in each group. Average decreases in treated adiposity and cellulite with accompanying improvement in dermoepidermal tissues were greater in the group treated with a low-calorie balanced diet plus cryolipolysis than in the diet only group.

Conclusions: cryolipolysis combined with bioactive currents produced measurable improvements at 8-week follow-up, even after only one treatment session. The ability to manage the controlled food program, by patients submitted to cryoliposculpt than others was better.

Keywords

Cryoliposculpt, cryolipolysis, cellulite, adipose tissue

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Introduction

Cellulite is a very common syndrome, universally characterized by the accumulation of localized adiposity and increased body weight^{1,2}. The condition is so prevalent (especially in women) that many studies have sought to determine whether it is a pathologic occurrence or should even be considered a chronic disease precisely because it is so common. Although it is very difficult to define a condition that is not considered pathologic, if a condition affects quality of life, it becomes pathologic. Scientific research tells us that although the genesis of so-called cellulitis is linked to causal, hormonal, genetic, circulatory, and lymphatic factors, it also depends on the subject's lifestyle.

In the last few years, different modalities have become available for the noninvasive reduction of adipose tissue, including radiofrequency and low-energy laser procedures, high intensity focused ultrasonography, and cryolipolysis³.

In March 2018, an American Society of Plastic Surgeons Report showed a rise in body shaping and non-invasive procedures; the statistics also reveal Americans are turning to new and innovative ways to shape their bodies, as minimally invasive cosmetic procedures have increased nearly 200% since 2000. More people are choosing to shape different parts of their bodies using ultrasound, radio frequency, infrared light, vacuum massage and injectable medication to reduce fat cells. Non-invasive procedures to eliminate fat and tighten the skin are gaining popularity, with the fastest growing procedure - cellulite treatments - up nearly 20% over last year 2017⁴.

The term *cryolipolysis* refers to the gradual and noninvasive cooling of adipose tissue to induce a process called *lipolysis*, or the breakdown of lipids.

Among these technologies, cryolipolysis has been studied most often, both in *in vitro* animal models and in randomized controlled trials involving humans^{5,6}.

Scientific studies have shown that under conditions of prolonged exposure to temperatures close to freezing, fat cells are more vulnerable to the effects of cold than surrounding tissues are⁷.

Other scientific articles have demonstrated that exposure to cold induces the apoptosis of fat cells and the production of cytokines and other mediators of inflammation that gradually eliminate the cells involved⁸. In the weeks after treatment, macrophages steadily digest the fat cells exposed to cooling, thus reducing the thickness of the treated adipose layer. The lipids derived from the cells are slowly released and transported by the lymphatic system for processing and elimination, as happens with fats derived from food.

Although inflammatory reactions and the *in situ* recall of cells responsible for the elimination of particles are triggered by cryolipolysis, the therapy does not alter blood chemistry values. This finding indicates that the technology is noninvasive compared with other techniques⁹.

The low rate of adverse effects associated with cryolipolysis is, in fact, the main reason doctors and patients prefer this technology over others⁷.

The first target of a body remodeling treatment is certainly to guarantee the best result, one that is tangible, lasting, and maximally safe in terms of

collateral risks¹⁰ and ineffective outcomes. In this study, we combined the destruction of adipose cells with the simultaneous emission of modulated currents (50-Hz pulses) to sculpt the dermal-epidermal profile (cutaneous), while improving the elasticity of the skin and preserving uninvolved tissues. The use of cold temperatures combined with a vacuum exploits the principles of cryogenesis and cryocyanogenesis, which act on areas with excess fat, facilitating its disposal. As stated previously, after treatment, an apoptotic process is triggered in the adipocytes, which leads to a natural, physiological death. The cells of the immune system determine the natural disposal of damaged adipocytes¹. Our approach to this retrospective study was to demonstrate the irrefutable and certain validity of cryoliposculpt treatment through the analysis of data and presentation of the results.

Materials and Methods

A total of 40 patients were involved in our retrospective study, divided into two cohorts. Inclusion criteria included an age between 20 and 66 years, presence of localized adiposity and so-called Cellulite (PEFS - Edematofibrosclerotic Panniculopathy), in diet treatment by weight loss with personalized diet. Exclusion criteria: patients in pregnancy / lactation, renal / hepatic insufficiency, previous cardiac pathologies and / or in pharmacological treatment.

For this study, recruitment of patients was ultimately based on choice of anatomic area and thickness of the fat layer and recognition that cryolipolysis is not recommended for everyone (ie, it is indicated for localized adiposity rather than for obese patients and is most suitable for "body sculpture"). All subjects were evaluated after undergoing a medical examination, an anthropometric examination, ultrasonography of the panniculus adiposus, and blood tests. Patients were assigned to one of two groups: patients who followed a balanced low-calorie diet only or patients who followed a balanced low-calorie diet and underwent a body rehabilitation protocol with cryolipolysis combined with bioactive currents in different areas (Cryoliposculpt).

Every 15 days the weight was checked and the measures of waist, hip, abdominal line, buttocks circumference, thigh root and thigh median were evaluated. Photographs were taken before and after the evaluation period because it has been shown that cryoliposculpt also induces action on fibroblasts over time¹¹. The evaluations of our retrospective and observational study were conducted at T0 (baseline) and at T1 (ie at 8 weeks from the beginning of the therapeutic program) as inspected by other studies in the literature⁷. All the raw data collected, of the anthropometric measurements already specified, have been elaborated and produced using statistically relevant graphs.

The cryolipolysis device used in this study is called Cryoliposculpt. It has unique technical characteristics that guarantee the efficacy and safety of the treatment while preserving cellular structures and their functionality. The applicator generates aspiration through an active vacuum, which sucks the treated area inside a cavity, where it comes into contact with two

cooling elements. These cooling elements reduce the temperature by 8°C to 10°C. A contact sensor constantly monitors the surface temperature of the skin to ensure safety and efficacy throughout the treatment (*Figure 1*). The active non-inertial vacuum, which is continuous and customizable (with respect to the mechanical resistance of the tissues), preserves local microcirculation. In addition to an inertial vacuum, the device allows delivery of a cycle of modulated microcurrents emitted in succession (spikes of current at 50 Hz) in a random way that does not induce adaptation in the cells. The microcurrents act on the extracellular interstitium, the microcirculation, and the remodeling and orientation of the collagen fibers without inducing a joule heating in contact with the tissues¹².

During treatment, the applicators were positioned on the area of the body where the patient hoped to reduce fat. An inverse thermal shock was applied to the underlying adipose tissue, cooling it to freezing, while avoiding other tissues. Although the tissues were under a negative pressure of about 30 mm Hg for 50 minutes during standard treatment, the constant mobilization of the tissue ensured there was no vascular damage or atrophy of the microcirculation; thus, no post-treatment massage was necessary¹³ (*Figure 2*).

The other Cryolipolysis machines on the market cause the formation of the “stick of butter” and, therefore, to avoid problems are matched as a result of the treatment or manual massages¹⁴ or shock waves to accelerate the process of ‘restitutio ad integrum’ of the treated tissues¹⁵.



Figure 1 - Cryoliposculpt treatment with 4 hand pieces.



Figure 2 - Patient abdomen immediately after treatment with cryoliposculpt.

Results

We enrolled a total of 40 patients with localized fat and cellulite (average age, 43 years). Of these, 20 patients were treated with a personalized balanced low-calorie diet and cryoliposculpt and 20 patients followed only a personalized balanced diet. After measuring the previously indicated areas (waist, hips, abdominal line, buttocks, thigh root and thigh median) at T0 and T1, in this retrospective study we observed in the cohort that performed both the diet and the cryoliposculpt, better results compared to the cohort that only performed the diet. All 40 patients performed a similar personalized diet. We observed that the cohort patients who did both the diet and the cryoliposculpt, were much more adherent and precise in following the dietary indications achieving better weight loss results. From the measurements measured at T0 and T1, in the areas already specified, we observed a quantitative improvement in localized fat deposits and treated cellulite (Figure 3). In patients treated with cryoliposculpt, we observed a marked improvement in the dermoepidermal tonicity of the treated areas. We verified with these patients the result obtained on a scale from 0 to 3 (0 = null result, 1 = discrete, 2 = good, 3 = excellent), which confirmed our observation. These observations were also confirmed by the photographic documentation carried out at T0 and T1, with frontal, rear, right lateral and left lateral views, using a standardized grid for the position of the feet. The evaluation of the photos was made by us doctors and by the patients themselves. Figure 3 shows the average measurements reported between T0 and T1 (ie, 8 weeks from the beginning of the therapeutic path), the period necessary to determine real results of the treatment⁷. We managed to reduce the average waist circumference by 3.65 cm with combined cryolipolysis and diet versus a 1.65-cm reduction with diet alone, a greater than twofold difference between the groups. The most striking and significant result was evident in the side area, with an average reduction of 4.55 cm in the combined cryolipolysis and diet group compared with 0.275 cm with diet alone, an approximately 16-fold difference between the groups. In the abdominal area, average reductions were approximately 6 cm and 1.7 cm, respectively. In the buttocks, average reductions were 7.9 cm and 1.4 cm, respectively. In the thighs, reductions of 3.35 and 2.625 cm were observed in the cryoliposculpt and diet group compared with reductions of 1.05 cm and 1.275 cm in the diet only group (Figure 4 and Figure 5). We therefore deduce that a therapeutic treatment program that includes cryoliposculpt and a balanced and controlled diet facilitated reductions in circumference in different areas of the body that were approximately 4 times greater than those produced by diet alone.



Figure 3 - Average reductions (in centimeters) of different anatomic areas between patients who were treated with a low-calorie diet alone and patients who were treated with cryoliposculpt in addition to the diet.



Figure 4 - Raw data and statistical evaluations of the cohort of patients treated only with the diet.



Figure 5 - Raw data and statistical evaluations of the cohort of patients treated with diet and cryolipolysis.

Discussion and Conclusions

The results of the present study suggest an important role of cryoliposculpt in the so-called cellulite, as association of cryolipolysis and active microcurrents for the improvement of the tone and texture of the treated tissue.

This new technique was shown to be a good and safe alternative to invasive treatments of adipose tissue¹⁶, even if it remains the gold standard.

Overall, the study demonstrated a reduction in different anatomic areas that was approximately four times greater than that obtained with diet alone.

The safety of all results obtained and efficacy of treatments, in a protocol tested worldwide, lets convallited non-invasive alternatives to body remodeling.

No adverse collateral effects were shown. Damage to and destruction of adipose cells was achieved without adverse effects to nearby tissues and vascular vessels while preserving all cellular functions of the treated tissues that were under mechanical stress and thermal shock inverted. Nerves and bones were also unaffected, and no changes were observed in the main organs of the body¹⁷.

Gradual improvements over time in the thickness of adipose tissues, illustrating the concept of systemic body remodeling, induced physiological - but nontraumatic - reactions in the body.

Overall, we observed greater improvements in areas with a large quantity of adipose tissue; in addition, the biological inflammatory process removed adipocytes over time and reduced the adipose layer.

Thus, adipose tissue freezing offers a potential new option for many people by remodeling the body without any invasive side effects¹⁸.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Disclosures

Michela Maggi, she is Biotec scientific consultant and was responsible for training in southern Europe Lumenis



Figure 6 - (A, B, C, D) - Pre and Post two months after treatment with Crioliposculpt and diet.



Figure 7 - (E, F, G, H) - Pre and Post two months after treatment with Crioliposculpt and diet.

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