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Research Article

Aesthetic-Therapeutic Applications and Physiological Effects of Cryofrequency

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Introduction: Cryofrequency is a non-abrasive and non-invasive aesthetic treatment method aimed at complaints related to localized adiposity and cutaneous flaccidity. The method consists of the generation of radiofrequency waves that in contact with the subcutaneous tissues produce heat. The differential of the cryofrequency is that this method uses a system of superficial cooling, producing a thermal shock by combining deep heat and superficial cold.

Aim: To understand the aesthetic-therapeutic and physiological effects of the cryofrequency method.

Method: This study is a bibliographical review. Thus, a search for specialized literature was made and the results were presented descriptively.

Results and discussion: The main aesthetic-therapeutic applications observed in the gathered studies are the reduction of flaccidity and body fat content. The main physiological effects are the shortening of collagen fibers, the production of new collagen fibers, and the death of adipocytes due to necrosis and apoptosis, both due to the effect of heat on the subcutaneous tissue.

Conclusions: We conclude that there is a good level of evidence regarding the use of cryofrequency, though studies of higher methodological quality are necessary to reduce the biases arising from the different types of equipment used and the subjectivity of the measures of outcomes adopted in the carried-out studies.

Introduction

Cryofrequency is a non-abrasive and non-invasive facial and body aesthetic treatment method that has been used relatively recently. The method enjoys wide dissemination in the various media, increasing acceptance by professionals in the fields of aesthetics and health, and so it has become a new alternative of treatment for people with complaints related mainly to localized adiposity and skin and muscle flaccidity [1,2]. The national companies and manufacturers responsible for the sale and dissemination of cryofrequency technology, as well as the products and devices that enable its application, defend the use of the technique, which according to them, allows the gain of immediate results, detectable since the first day of application [2,3].

The method consists in the generation of radiation called radiofrequency, a range of the electromagnetic spectrum that goes from 3 Hz to 300 GHz, and the consequent deposition of thermoelectric energy on a given treatment area [4]. This radiation is said to be non-ionizing due to the low levels of energy produced from the generation of electric current so that its effect on the organism is purely thermal. The difference between cryofrequency and classic radiofrequency revolves around the existence of a cooling system in the cryofrequency apparatus. The term "cryofrequency" is mainly used in Brazil, whereas on a worldwide scale the most used term is radiofrequency, in this case, associated with a cooling system [4].

Radiofrequency has been used in medical treatments for almost a century, especially for surgery and ablative procedures. However, as a non-ablative aesthetic treatment, that is, performed without the need of destroying the epidermis, its use dates back to more recent decades [5]. Most treatments utilize frequencies of up to 10 MHz, being this parameter the most important once it relates to the depth at which the energy reaches the tissue [5].

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Cryfrequency is applied in at least two distinct but complementary manners. The first manner is the application of monopolar, bipolar, and/or multipolar electromagnetic waves in an isolated or combined manner with intensity enough to generate heating around 60°C deeply in the dermis and hypodermis through a mechanism of energy conversion that occurs from the inside out of the tissues. And, the second manner is the simultaneous cooling (around -10°C) on the surface of the skin that is produced by the cryofrequency apparatus [2,6]. It is argued that this combination of high and low temperatures causes a sort of thermal shock, which would be one of the main mechanisms behind the therapeutic effects of the method.

According to cryofrequency supporters, that thermal shock leads to the destabilization of local metabolism, causing physiological changes that ultimately result in aesthetic benefits. The main aesthetic-therapeutic benefits of its application would be the immediate "lifting" of the skin and the breakdown and absorption of adipose tissue, in this manner combating tissue flaccidity and localized adiposity simultaneously, as well as related aesthetic complaints with similar pathophysiological mechanisms. The physiological effects evoked by the application of cryofrequency are related to changes in local metabolism such as vasodilation and increased oxygenation, contraction of collagen fibers, renewal of collagen, and apoptosis of adipose cells [2,3].

The method is applied over any region of the face and the body, in areas such as the glutes, arms, back, legs, flanks, abdomen, face, and neck. It is referred that cooling the epidermis causes a comfortable sensation, minimizing any discomfort caused by the deep heating of the tissues. Thus, in the most current radiofrequency devices, the coupling of an infrared thermometer allows the monitoring of the tissue temperature, which leads to a safer application of the radiofrequency waves during treatments. These treatments are usually carried out in sessions that last around 30 minutes and are done weekly or with a specific periodization according to the body region and the treatment objectives [2,3].

As general prerogatives, the patient needs to be in good eating and hydration habits so that the results of the treatment become evident. Furthermore, it is recommended that cryofrequency is used in conjunction with other aesthetic treatments, maximizing the effects, and improving the general aspect of the treating area [7]. Since it is an electrotherapeutic treatment, cryofrequency has the classic contraindications cited in the specialized literature and also emphasized by the manufacturers of the thermoelectrotherapy devices, to name some: use of pacemakers, metal and silicone implants in the area to be treated, neoplasia, dermatitis, epilepsy, pregnancy, etc [8].

Considering the widespread use of cryofrequency by professionals in the fields of aesthetics and health, as well as the wide dissemination in media and market on its short-onset and long-duration benefits, a critical exposure about this method must be made with an adequate description of its effects, both observed in clinical practice and experimentally proven by scientific studies. As a result, the use of the cryofrequency method may be used wisely, rationally, and safely, based on evidence.

To this end, we present here a review of the literature, with an emphasis on scientific sources that deal with the cryofrequency method (including radiofrequency with cooling systems). This article is divided into three parts. The first part will deal with the aesthetic-therapeutic applications of cryofrequency. The second part will address the physiological effects underlying these applications. Finally, the third part will take a look at the scientific evidence available around the use of cryofrequency.

Method

A bibliographic review was carried out with a search for articles, book chapters, and other specialized sources related to the topic under study. It was considered sources from the last two decades, and older if regarded important to clarify the topic. Most of these were from English-language sources. However, as cryofrequency seems to be a market brand in Brazil, we have also considered articles written in Portuguese, which were very few. The search for sources of scientific information took place manually and electronically, and all articles, books, and other electronic or printed sources considered relevant for this research were included in the review. From the entire bibliography found, 23 sources among articles and book chapters were subjected to screening by relevance and then included for reading. The results are presented in a descriptive and summarized way under the subtopics presented in the next sessions and discussed simultaneously.

Results and discussion

Bibliographic collection of the aesthetic and therapeutic applications of cryofrequency. From the collected and analyzed data, it is possible to identify two main therapeutic applications of cryofrequency. They are the use of the method to reduce tissue flaccidity for both the face and the body and other complaints related to aging, especially wrinkles, and the application of cryofrequency to reduce body measures, that is, to reduce localized adiposity. Besides these two main applications, cryofrequency has also been used for a wide range of other aesthetic and functional complaints, such as in the treatment of cellulitis and non-aesthetic dysfunctions [9].

A study that received much attention for having provided the basis for the approval of the use of radiofrequency as a face treatment by the Food and Drug Administration of the United States of America in 2004 was the study carried out by Fitzpatrick and collaborators [10]. This study with 86 participants showed that monopolar radiofrequency (with superficial cooling) applied only once led to a reduction in periorbital wrinkles and skin flaccidity in the supraorbital region, in addition to a high level of satisfaction by the participants (assessed using objective and subjective measures). It is interesting to note that that multicenter study indicated that the results persisted 6 months after the end of treatment. That study is aligned in its

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quantitative results with the controlled clinical study carried out by Bassichis, Dayan, and Thomas [11], which showed that cryofrequency was able to decrease the flaccidity of the upper third of the face, which, on the other hand, was not correlated with the participants' perception of improvement, unlike the aforementioned study.

A more recent pilot study, although not controlled and with a reduced sample (20 subjects), showed high to moderate results in the reduction of the periorbital region, even six months after the end of the study [12]. Similar results have also been reproduced in other studies with greater methodological limitations [13-15]. Previous searches of the literature on the use of radiofrequency with a cooling system pointed out that the method was effective in the treatment of localized adiposity and body remodeling [5].

In one of these studies, eight treatment sessions with a one-week interval were carried out. It was applied to the regions of the abdomen, thighs, and buttocks for sessions of 20 minutes (39-42°C, 0.8-2.45 MHz, variable intensity). The evaluations consisted of photographs at different time points before and after the intervention, measurement of the circumferences of the treatment regions, and the rate of participants' satisfaction (24 individuals). After the study, clinical improvement of moderate to high was observed in 79% of the sample, with reduced circumferences and a significantly high satisfaction rate. It is noteworthy that the results were still preserved 3 months after treatment [5].

Similarly, Fajkošová and collaborators [16], conducted a study with 40 healthy individuals with abdominal and hip adiposity. The treatment was performed once a week for 30 minutes per session, adding up to four sessions. Participants were subjected to evaluations of objective measures, such as the circumference of the treatment regions and also to satisfaction questionnaires. As a result, they observed that 32 subjects had a significant 1-13 cm reduction in waist circumference.

A more recent study evaluated 11 women who underwent radiofrequency localized adiposity treatment for ten sessions and conducted a pre- and post-treatment analysis. They concluded that the intervention was able to reduce the supra and infra umbilical abdominal measures, being statistically significant with outcomes also confirmed by adipometry. This study also shows improvements in body image perception and good satisfaction rate of the participants [17]. However, this study does not make it clear whether the device used had an epidermis cooling system.

In general, the literature on cryofrequency in the treatment of adiposity appears to lack some important aspects of methodological quality, such as samples large enough to detect the effect size and the use of control groups and sample randomization. This is a very important issue that must be met, especially given the wide appeal of the aesthetic market for the use of the method to reduce measures.

Some other studies seem to indicate positive effects in the application of cryofrequency in the treatment of cellulitis and the signs of facial aging (rejuvenation). For example, Sartori et al. (2017) [18], conducted a study with eleven women complaining of second- and third-degree cellulite in the gluteus region. Ten sessions were applied with a minimum interval of 24 hours, with the evaluation of objective measures through cirtometry of the region of the flanks, hips, and breeches, as well as graduation tests for cellulitis and photographs. The results, in general, point out improvements in the aspects of cellulitis. However, the small sample size of the study, the use of some non-objective measures, and the absence of a control group limit the generalization of the results.

Bibliographic collection of the physiological effects of cryofrequency

Overall, the physiological effects of the method consist of the classic thermal effects of electrothermotherapy: vasodilation, increased oxygenation, and removal of debris in the tissues [8]. However, in the case of cryofrequency given the concomitant cooling of the epidermis, many have attributed some physiological effects to the so-called thermal shock caused by the "encounter" between the two stimulated temperatures: cold on the skin surface and more intense heat in the dermis. This is because radiofrequency generates heat when it encounters tissues. Thus, the greater the resistance of these tissues to electrical current, the greater the intensity of heat generated. Besides, heat spreads more deeply into the skin from the water present in these tissues. The heat then diffuses through the tissues in a three-dimensional manner with depth controlled according to the parameters of the energy source and the cooling system [6].

The ability of heat to cause collagen denaturation and the consequent neocollagenesis is widely accepted and proven, thus representing one of the main physiological effects of cryofrequency. This effect is of high clinical and aesthetic value since during the aging process there is a important loss of collagen content and an increase in elastin, leading to the condition of flaccidity both at the cutaneous and at the muscular levels [6,19]. Hsu and Kaminer [13], based on animal models, observed that the heating of the skin layers leads to the denaturation of collagen and the consequent stiffening and shortening of collagen fibrils, in addition to the increase in fibroblastic activity and neocollagenesis during many months after initial applications. This is because when properly heated the collagen fibers change their conformation, contracting due to the breakdown of hydrogen bonds, assuming a more stable structure and shortening the collagen fibers. These molecular processes are responsible for the "lifting" or skin tightening effect. The final effect of that is a more robust and youthful appearance of the skin [9,19].

Thus, the insufficient increase in the temperature of subcutaneous tissues does not affect collagen, while at the other extreme, excessive heat can lead to cell death and protein denaturation and the consequent healing process. However, the mild lesion generated by a moderate amount of heat seems to lead to the production of a new base substance in the dermis, with tissue remodeling and an observable histological

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and clinical effect [6,19]. It has also been observed that heat stimulates fibroblasts to produce collagen, which makes the deposition of type 1 collagen and its reorganization the main mechanism behind that remodeling.

It is indicated that the collagen shrinkage temperature is between 57 and 61°C. In millisecond exposures this optimum temperature rises to 85°C, and for longer exposure times (of many seconds) this temperature may be between 60 and 65°C [6]. So, it can be assumed that there is an optimal combination of exposure time and temperature for an effective and safe result, associated with appropriate protection of the epidermis, which occurs due to the cooling caused by the cryofrequency device before, during and after the generation of heat. The physiological mechanism of cryofrequency is, therefore, of two natures: the immediate contraction of collagen (which is immediate to its denaturation) and the natural curative response of the organism that involves remodeling by collagen deposition and the subsequent increase in its density [20].

The reduction in localized adiposity is mainly attributed to the breakdown of fat caused by the deposition of heat. The underlying cellular process would be the apoptosis of fat cells, that is, there would be a programmed cell death process in the tissues treated with cryofrequency. Thus, there would be a reduction of reserve fat in tissues due to the high internal temperature, so that triglycerides would be broken down into fatty acids and glycerols, a process called lipolysis [8].

A clinical study by Franco and colleagues [21], was able to show that the availability of fat cells decreased markedly after the application of radiofrequency during 1 to 3 minutes of treatment (from 89% to 20%) and that this result was related to the temperature intensity reached in the hypodermis. Despite not using a superficial cooling system, no harmful effects were observed in the most superficial layers because the radiofrequency produced a heat gradient, with an ever lower intensity until reaching the epidermis. The study also attested to the occurrence of vascular changes (vasodilation, congestion) after the fourth day of treatment and adipocyte necrosis on the ninth day of treatment within 4.5-19 mm of skin depth.

The study by McDaniel and collaborators [22], used a pig animal model to study the effects of monopolar radiofrequency on reducing abdominal fat. This study demonstrated the method's ability to generate deep heat and complete preservation of the epidermis simultaneously. Using histological analysis, they proved that the process of apoptosis of adipocytes does occur in the tissues under treatment, with mild signs of inflammation in the treated area. They concluded that an 11-minute treatment was sufficient to cause adipose tissue breakdown in a 20cm x 10cm treatment area, which occurred at increasing rates in subsequent treatment sessions with a peak of up to 53% in the apoptotic index. Thus, both the process of necrosis due to adipose tissue injury and the process of apoptosis is behind the physiological effects of applying cryofrequency to reduce localized adiposity.

Although the effect of the thermal shock generated by cryofrequency devices may affect the outcomes of the treatment, the aforementioned study [22], did not attribute the observed effects to the temperature shock, but the high temperatures reached in the subcutaneous tissues. The cooling of the epidermis was used to protect the layer from the harmful action of these high temperatures. The main effects produced by cryofrequency, namely, shortening of collagen fibers, neocollagenesis, and the death of fat cells seem to be responsible for the range of benefits observed in the treatments [23].

Analysis of available scientific evidence

Many devices aimed at aesthetic treatments are built and perfected very quickly, in many cases much faster than the ability of scientific studies to be carried out and have the prerogatives of a treatment's clinical effects analyzed. Therefore, when research data finally becomes available, these devices are already outdated or have already been widely used by consumers [6]. Users and professionals in the field of aesthetics and health need to use rationality and clinical experience in choosing the treatments that their clients and patients will undergo. The dissemination in the field of aesthetics is growing and it often seems to disregard or minimize possible negative effects of the use of devices with clinical evidence not yet established.

With the advance of scientific studies, it is possible to make a better choice about which parameters to use, the better number of sessions of treatment, or even not using it in case that clinical studies have shown its ineffectiveness. In this review, it was observed that although there are a relatively high number of studies on cryofrequency, these in large part used different devices with diversified technology, particular technical specifications, and different application modes (monopolar, bipolar, multipolar), etc. It limits the comparison of studies and the generalization of the results.

Older studies report the occurrence of some side effects related to the use of the devices and the application of radiofrequency, such as burns, erythema, mild edema, inflammatory process and pain [10,13,14]. However, with the improvement of that technology, many of these events have been minimized. With the advancement of refrigeration systems attached to the device and monitoring through the coupling of infrared thermometers, burns and pain are no longer common events, making the application of the method easier to be applied by the practitioners and safer for the users [9].

Considering all the evidence discussed here, we can see that there is a solid basis for confirming the aesthetic and physiological effects usually attributed to cryofrequency treatment. In any case, many studies still need to improve their methodological quality. One previous literature review [6] showed that the level of evidence from the studies carried out so far was still low (considering 12 studies). Even studies with good quality still do not often meet sample randomization methods and/or do not use control groups. Another observation that can be made is that many of those studies usually use subjective

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measures, such as before-and-after approaches, photograph visual analyses, and self-perception questionnaires as the lead method of evaluating the treatment effects. However, in recent years an increasing number of studies with better experimental designs have been carried out. Some of these studies, as mentioned in the present review, made good use of more objective outcomes associated with subjective measures (individual satisfaction, self-perception of improvement, etc).

Conclusions

The purpose of this review was to search the specialized bibliography for both the aesthetic-therapeutic and the physiological effects of the cryofrequency method, and finally to analyze the evidence surrounding it. It was found that cryofrequency or the application of radiofrequency with concomitant cooling of the epidermis has at least two main applications: reduction of skin flaccidity and localized adiposity. The evidence that cryofrequency is effective in reducing these aesthetic complaints comes from both animal and clinical studies, although many of the clinical studies still have limitations regarding the experimental design and the evaluation method. Higher methodological quality studies are therefore necessary to reduce the biases arising from the different types of cryo/radiofrequency devices and consequently support its use.

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