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Radiofrequency for the treatment of skin laxity: mith or truth^{*}

[Angélica Rodrigues de Araújo](#),¹ [Viviane Pinheiro Campos Soares](#),² [Fernanda Souza da Silva](#),³ and [Tatiane da Silva Moreira](#)⁴

¹Pontifícia Universidade Católica de Minas Gerais (PUC Minas) – Belo Horizonte (MG), Brazil.

²Universidade Federal de Minas Gerais (UFMG) – Belo Horizonte (MG), Brazil.

³Faculdade Ciências Médicas de Minas Gerais (FCMMG) – Belo Horizonte (MG), Brazil.

⁴Private Clinic – Belo Horizonte (MG), Brazil.

MAILING ADDRESS: Angélica Rodrigues de Araújo, Instituto de Ciências Biológicas e da Saúde/
Departamento de Fisioterapia – PUC-Minas, 500, Dom José Gaspar Av. Coração Eucarístico, 30535-901 - Belo Horizonte - MG, Brazil. Email: angelica@bios.srv.br

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Abstract

The nonablative radiofrequency is a procedure commonly used for the treatment of skin laxity from an increase in tissue temperature. The goal is to induce thermal damage to thus stimulate neocollagenesis in deep layers of the skin and subcutaneous tissue. However, many of these devices haven't been tested and their parameters are still not accepted by the scientific community. Because of this, it is necessary to review the literature regarding the physiological effects and parameters for application of radiofrequency and methodological quality and level of evidence of studies. A literature search was performed in MEDLINE, PEDro, SciELO, PubMed, LILACS and CAPES and experimental studies in humans, which used radiofrequency devices as treatment for facial or body laxity, were selected. The results showed that the main physiological effect is to stimulate collagen synthesis. There was no homogeneity between studies in relation to most of the parameters used and the methodological quality of studies and level of evidence for using radiofrequency are low. This fact complicates the determination of effective parameters for clinical use of this device in the treatment of skin laxity. The analyzed studies suggest that radiofrequency is effective, however the physiological mechanisms and the required parameters are not clear in the literature.

Keywords: Esthetics, Radio waves, Rejuvenation, Skin aging

INTRODUCTION

In recent years, concern with body has gained much importance in society, because beauty is reflected in self-esteem and quality of life.¹ This fact contributed to the growth of the search for beauty treatments.

Among the unesthetic disorders, laxity, especially in the skin, is one that has great impact on the function and quality of life.² A lax tissue is the result of biomolecular changes, and the damage due to collagen fibers change is closely involved in this process.³

Currently, there are several strategies, invasive and non-invasive, to treat unesthetic disorders.^{4,5} Despite relatively better results of invasive treatments, the sequelae and the complications that may be caused by them lead to increasing search for non-invasive or minimally invasive procedures.^{6,7}

Among the non-invasive procedures, those that use electromagnetic fields (EMF) to directly or indirectly influence cells stand out.^{8,9} Nonablative radiofrequency (RF) is one of the commonly used procedures, especially for the treatment of skin laxity. This is a therapeutic modality that produces a selective and controlled rise in tissue temperature from a high frequency alternating current (0.3 to 10 MHz). The rising of temperature and the depth of heating depend on the level of energy used and on the impedance of biological tissues.¹⁰ The final goal is to induce thermal damage to stimulate changes in collagen conformation and produce neocollagenesis in deep layers of the skin and subcutaneous tissue.¹¹ However, literature is not unanimous in relation to the occurrence of these benefits.¹²

Controversies regarding nonablative RF, beyond purely scientific discussions, also involve economic questions - i.e. market interests that, in the field of healthcare focused on esthetic, are very strong. This fact is evident when observing the explosion of RF equipment designed for beauty treatments in the market (national and international). Many of these devices have not yet tested parameters and they aren't accepted by the scientific community, which may represent a serious risk to the user's health.¹³ Therefore, it is necessary to review the literature regarding the physiological effects, the appropriate parameters for the use of nonablative RF and the methodological quality and level of evidence of the studies. Additionally, analysis of the equipment available on the market allows the performance of safe and effective applications in the clinical practice.

METHODOLOGY

Search strategy

A literature search was conducted from August 2013 to December 2013 in six databases (MEDLINE, PEDro, SciELO, PubMed, LILACS and CAPES), using the keywords "facial rejuvenation", "skin rejuvenation", "skin tightening", "laxity", "cutaneous remodeling", "body shaping", "body contouring", "skin contraction", "rhytides", "radiofrequency non-ablative", "radiofrequency nonablative" and "radiofrequency non-invasive". In addition to the electronic databases, the search was supplemented by a manual search, which had the bibliography of previously selected articles as reference.

Inclusion criteria

Type of study Experimental studies, published between January 2000 and December 2013, in English and Portuguese, which had full text, were included.

Participants

We selected studies carried out on humans, both sexes, diagnosed as facial or body laxity.

Intervention

Studies that used nonablative RF devices as treatment for facial or body laxity were included. Studies that used other associated therapies were included only if the effect of nonablative RF could be identified separately.

Exclusion criteria

Studies in animals or that used combination therapy or ablative RF as a treatment for skin laxity were excluded from the review.

Data extraction

Four independent reviewers selected the articles by title and abstract. If this provided enough information for inclusion, a complete copy of the text was requested. In the presence of differences between examiners, these get together to reach a consensus. If the disagreement remained, a fifth person was invited to address the problem.

Characteristics, methodological quality and level of evidence of studies

Selected studies were organized into a table for the general characterization of the study and facilitating of the analysis of methodological quality and level of evidence. Data regarding objective, sample size, study groups, analyzed endpoints, measuring instruments, obtained results and justification for the study were gathered.

For the assessment of the methodological quality of the articles we used PEDro scale¹⁴ (Physiotherapy Evidence Database) and to analyze the level of evidence we used the criteria proposed in the work of Reid and Rivett (2005), adapted for this study.¹⁵

Treatment parameters

Data related to the treated area, technical specifications of equipment used, parameters (frequency, power and temperature) and treatment protocol were selected and analyzed.

Market analysis

We investigated the relationship between what is advocated in the literature for the use of nonablative RF, comparing it with what is offered by nonablative RF equipment available in Brazil and abroad. It was observed that the equipment allow the adjustment of the parameters and techniques for safe and effective intervention. A survey in the instruction manual and/or contact with the manufacturer was carried out to acquire the technical characteristics of the devices.

RESULTS

Literature search yielded a total of 139 articles. Of these, 62 were selected and 32 were excluded, remaining 31 studies for review.^{6,12,16-44}

Characteristics, methodological quality and level of evidence of studies

Main characteristics of the studies are summarized in [table 1](#). It's possible to note that the sample used was composed predominantly by women (95.17%), aged between 35 and 65 years. Most studies (96%) had no control group, and only in Bassichis et al study (2004) the results were analyzed through a comparison with a control group.²⁰

Table 1

Characteristics of studies selected for research

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Primary endpoint assessed in the studies was facial laxity (61%), followed by wrinkles (28%) and body laxity (11%), evaluated in the arms, abdomen, thighs and buttocks. To analyze the endpoints, pictures (face laxity: 51%; wrinkles: 52%; body laxity: 50%), customer satisfaction questionnaire (face laxity: 27%; wrinkles: 23%; body laxity: 25%), Fitzpatrick scale (face laxity: 7%; wrinkles: 9%), forehead height measurement (face laxity: 4%) and biopsy (face laxity: 3%; wrinkles: 14%; body laxity: 25%)

were used.

Although majority of studies (96%) report positive results in treating skin laxity using RF, only 44% showed statistical significance. In other studies, results were described quantitatively. In 100% of these studies, authors explained the results by positive thermal effects caused by RF.

All reviewed articles reached grade ≤ 4 on PEDro scale.¹⁴ Main problems were lack of control group (96%), no secret allocation (100%) and no blinding of subjects, therapists and evaluators (100%). On the analysis of level of evidence, it was observed that 88% of the studies presented limited methodological quality, suggesting insufficient scientific evidence of the benefits of nonablative RF regarding skin laxity.

Physiological effects

The main physiological effects observed in the studies were the contraction of collagen (short-term effect) and the stimulation of collagen synthesis through the tissue repair process (long-term effect).

Parameters of study treatment

The most used equipment was Thermacool (THERMAGE), used in 52% of trials. Regarding the frequency of electromagnetic waves, there was a wide divergence. However, there is a tendency to use 6 MHz frequency, observed in 64% of trials.

The thermal power was the parameter that showed more divergence. Forty-six percent of the studies used the maximum power of 330 W; 25% did not mention the power used or data as application time and size of the nozzle that would enable the calculation thereof. In other studies there was great variation of this parameter. No study measured the temperature in RF therapeutic target, the dermis, and the values were measured only in the epidermis. Sixty-four percent of reviewed studies maintained the temperature range in the epidermis between 35° C and 45° C and 36% didn't measure the temperature range.

Regarding the treatment time, it was observed that there was no standardization, ranging from one to 24 weeks. There was, however, a tendency toward only one session (25.92%). In 18.5% of the studies, the treatment time was not specified.

The area (face or body), and the processing parameters used in each study are summarized in [table 2](#).

Table 2

Area treated and parameters used in the selected studies for research

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Market analysis

Analyzing RF equipment available in the market, both in Brazil and abroad, a great variability in relation to the parameters offered by the equipment and the modulation range of these parameters can be observed, especially in relation to the frequency of electromagnetic waves and the thermal power.

Not all devices provide in their manuals data or technical specifications of the radiation used, and even after contact by e-mail it was not possible to have access to this information.

Most of the devices found on the market are international.⁴⁵⁻⁵⁶ According to information collected in the respective manuals and websites of manufacturers, the frequency varies from 1 MHz to 6 MHz and the power ranges from 40 W to 240 W. Most of these equipment allows power settings according to the treated area. RF application in each region takes about 2.5 seconds. Manuals also mention that, during the treatment, the temperature in the epidermis is maintained at 40° C, whereas in the dermis it ranges from 50° C to 75° C. The form of energy transmission to the tissue is through the capacitive method, with bipolar, tripolar or multipolar electrodes. The main side effect is pain during treatment, and to minimize it the patient receives a topical and/or oral anesthetic.

In Brazilian RF devices, according to their respective manuals and manufactures websites, the frequency, in most of equipments, varies between 0.64 MHz and 8 MHz, and 1 device works with the frequency of 27.12 MHz.⁵⁷⁻⁶³ The power used ranges from 50 W to 150 W -lower than the international equipment and without the possibility of adjustment during treatment. Treatment time ranges from 5 to 10 minutes per unit area (10 cm² quadrants) and the temperature is maintained at 40° C in the epidermis. According to the manuals, in the dermis the temperature is around 60° C and the treatment is painless, with no the need for using anesthetics. Despite this statement of manufacturers, in clinical practice it is possible to note that the application of RF is not completely painless and discomfort can be felt due to the temperature rise. The form of energy transmission to the tissue is through capacitive method (bipolar, tripolar or multipolar electrodes) in most equipments; two equipments^{59,63} use inductive method (monopolar electrode).^{57,59-63}

Characteristics of the equipment on the market are summarized in [table 3](#).

Table 3

Characteristics of national and international radiofrequency devices

[Open in a separate window](#)**DISCUSSION**

Skin aging may be divided into 2 processes: intrinsic and extrinsic aging or photoaging. The first is a natural, slow and gradual process. The second is exacerbated by environmental factors such as improper exposure to sunlight. Both are accompanied by changes in morphological and biomechanical properties

of skin.⁶⁴ The main clinical characteristics of aged skin are increased rugosity and loss of elasticity (laxity). Human dermis consists mostly of type I collagen, composed of 3 polypeptide chains stabilized by a triple-helical conformation.¹³ Using the microscope, it is observed that with age there is an increase of collagen network density and reduced stability of cross-links.^{13,65} Elastin, the main component of elastic fibers in the dermis, shows signs of decrease of its function, providing less resistance and traction capacity. Atrophy of subcutaneous fat is also noted.⁶⁵

Among the non-invasive procedures for treating skin wrinkles and laxity, RF is one of the most widely used.¹¹ The objective of RF is to stimulate changes in collagen conformation and induce neocollagenesis by thermal power generation in deep layers of the skin and subcutaneous tissue.⁹

It was observed in this study that EMF can act on tissues in several ways, causing thermal and/or athermal effects. Several authors cite as thermal effects, caused by the increase of local tissue temperature, the contraction of collagen and the stimulus to the synthesis of collagen fibers.^{12,17,21,25} The literature also cites some athermal effects, where EMF could induce biological changes through interaction with cellular membrane receptors or channels. According to Bachl et al (2008)⁸, EMFs are able to stimulate the synthesis and cytoprotective growth factor. Goodman et al (2002)⁶⁶ mention the increasing of enzyme activity, level of transcription of specific genes and mRNA expression. Tokalov et al (2004)⁶⁷ reported, on their experiments with human cell cultures, that EMF leads to a significant induction of heat shock genes. Alvares et al (2008)⁶⁸ also mention the effects on the synthesis of mucopolysaccharides and elastic fibers, which leads to dermal thickening, thus improving firmness and elasticity of the skin. In the studies reviewed, all authors credited the results observed only to the thermal effects caused by RF, without taking into account other actions promoted by EMF. However, only 12% of the studies used an objective instrument (biopsy) for establishing the therapeutic changes promoted by tissue heating, and most of the outcomes were evaluated through subjective data such as photographs or perception of the patient - very inaccurate measurements to validate the results.^{21,22,30,38}

The reviewed literature mentions that RF for the treatment of skin laxity and wrinkles is founded on the use of a source of heat for denaturation of collagen (which occurs at temperatures ranging from 50° C to 75° C in the dermis) and the consequent contraction of the connective tissue.^{9,10,69} These processes lead to tissue repair response, establishing long-term dermal remodeling. Zelickson et al (2004) demonstrated, through abdominal skin biopsies, that 8 weeks after the denaturation of collagen there is an induction of new collagen synthesis (neocollagenesis).⁷⁰

According to Ruiz-Esparza et al (2003), the amount of synthesized collagen depends on the heating intensity of the connective tissue.³³ Collagen protein is a compound of 3 polypeptide chains, which are involved in a triple helix structure. The process of thermal contraction of collagen begins with denaturing the triple helix, where the intramolecular cross-links are broken and collagen undergoes a transition from a highly organized crystalline structure to a gel-like state (denaturation). The collagen contraction occurs by the cumulative effect of the "unwinding" of the triple helix due to the destruction of intermolecular cross-links and the residual stress of such links.⁶⁹ According to Ruiz-Esparza et al (2003), the thermal effects of RF can change the shape, the length and the diameter of the collagen fibers for the reorganization of collagen.³³

In order to have an effective effect of RF in the treatment of skin laxity and wrinkles, it is vital to have knowledge not only of skin aging process, but also of parameters to be used, such as frequency and device power, treatment time and temperature maintained in the skin. Researches advocate the need for the use of appropriate parameters for the achievement of the therapeutic results of the RF, since the effects induced by EMFs are dependent parameters.^{8,71} This review observed that there is no report of

standardization of the way to reference these parameters in the literature and, often, they are not made available from manufacturers of RF equipments.

Alvares et al (2008) studied changes in tissues, cells, thickness and structure of pigskin after each RF section and 2 months after the last application.⁶⁸ The most significant changes were found 2 months after the last application. In biopsies taken after each session, it was observed that the papillary dermis was expanded due to edema and vascular congestion, followed by an accumulation of intercellular substance. In biopsies after 2 months of the last application, an increase in the amount of collagen, elastic fibers and mucopolysaccharides was noted.

The thermal power applied by the devices of the studies was the parameter that showed a greater difference. In 46% of the studies, the maximum power used was 330 W, and in 29% it presented a great variation of the adopted values. In other studies, the power was not mentioned or data that allowed the calculation of this variable were not provided, as well as application time or size of the nozzle used for treatment. Zelickson et al (2004) performed a dose-response study evaluating the efficacy of a RF device in the treatment of skin laxity in the abdominal area.⁷⁰ Authors confirmed, by histological analysis, that using a power of 78 W showed significantly better results. There was a change in the areas of collagen fibers, with increased diameter and amount of type I collagen, after 8 weeks of treatment. Analysis of the power used is important since the conversion of electrical energy into thermal energy occurs due to the power supplied and the impedance of the tissue.⁷²

The frequencies used in the reviewed studies ranged from 1 MHz to 6 MHz, with the highest percentage of studies reporting a frequency of 6 MHz. According to Abraham and Mashkevich (2007)⁷³, during the treatment cycle with an EMF at 6 MHz, it is determined that polarity alternates, at a rate of 6 million cycles per second, what stimulates the movement of charged particles and creates an electrical current within the tissue treated by attracting and repulsing electrons and ions. Through resistance of the tissue to this flow of particles occurs heat generation.¹¹ The higher the frequency of EMF and the lesser vascularized the tissue, the greater will be the production of heat.

The literature reports that the penetration depth of RF is an inverse function of its frequency, that is, in lower frequencies (0.8 MHz) occurs a greater penetration and in higher frequencies (2.45 MHz), a lower penetration.¹⁰ Zelickson et al (2004)⁷⁰ mention, however, that it is possible to change the depth of penetration of the treatment by changing the electrode geometry, the amount of power supplied and the duration of treatment.

The tissue temperature is another key parameter for achieving therapeutic goals with RF and is directly influenced by the characteristics of the tissue.^{11,74} RF energy is conducted electrically to the tissue. Heat is generated when the inherent tissue resistance (impedance) to the passage of electrons converts the electric current to thermal energy. This reaction is determined by Ohm's Law: Energy (J) = $I^2 \times R \times T$ (where I = current, R = tissue impedance and T = time of application). High impedance tissues, such as subcutaneous fat, generate more heat.⁷⁵ Several experiments with tendons, joint capsules and skins of different species (rat, bovine and human) have established that collagenous tissues suffer distortion when exposed to temperatures ranging from 65° C to 85° C.⁷⁶⁻⁷⁸

In all the analyzed studies, the authors mention the need to reach high temperatures in the dermis in order to achieve therapeutic goals. In this review, however, none of the authors measured the temperature of the therapeutic target, the dermis. There are reports on the temperature measurement in the epidermis, which remained around 40° C and 42° C, and allusions on that in the dermis the temperature would be around 65° C. To date the application of RF viability with dermal heating and preservation of the epidermis was studied only by using a three-dimensional mathematical model.⁷⁹ No scientific evidence of studies in humans that could reliably quantify the temperature of RF target was

found. This fact undermines the decision-making and does not guarantee the effectiveness of treatment.

Some of the reviewed studies performed histological analyzes, whose findings show benefits of RF in increasing collagen production, thus reducing wrinkles and skin laxity.^{21,22,30} It is noteworthy, however, that in the studies of Montesi et al (2007)³⁰ and Kaplan et al (2009)³⁸ results were based only on quantitative data, with no statistical analysis.

Through the analysis of RF equipment available in the market it was revealed that international equipments, at first, seem to allow the modulation of parameters closer to those required to obtain significant changes in collagen. There aren't, in the surveyed databases, studies proving the effectiveness of Brazilian RF equipment, despite the benefits reported by manufacturers and the fact that these equipments are frequently found in clinics and medical offices in the country. Furthermore, by analyzing the manuals of these equipments, we observed that the power used is fixed and lower than that of international equipments used in the assessed studies. These data suggest that the physiological effects resulting from the use of RF can't be achieved with these equipments.

Regarding the frequency of electromagnetic waves, we noted a difference on the frequencies of the equipment used in the studies analyzed and those on the market (national and international). In studies with positive results there was a predominance of 6 MHz frequency, differently from the frequencies often cited in the manuals of equipments available on the market, which was 1 MHz. In one of the assessed equipments, the frequency reported by the manufacturer (27.12 MHz) diverges from other equipments.⁴⁷ Frequency of 27.12 MHz is used in RF equipment commonly employed for the treatment of trauma and orthopedic disorders. In the manual of this equipment, this potency is justified by the demands made by international and national bodies, such as the Federal Communication Commission (FCC) and Agência Nacional de Telecomunicações (ANATEL), with the frequencies 13.56 MHz, 27.12 MHz and 40.68 MHz designed for medical applications. However, there is no data to confirm benefits of these frequencies on skin laxity or wrinkles.

Most equipment use capacitive method (bipolar, tripolar or multipolar electrode) for transmitting energy to the skin. According Montesi et al (2007)³⁰, the main difference between the inductive and the capacitive method is the configuration of the electrodes to be applied to the skin, which will result in the way energy is transmitted to the tissues. The inductive method (monopolar electrode) uses an active and a passive electrode, the latter acting as a grounding electrode. Power is transmitted to the tissue via a single point of contact, which increases the penetration of the generated current. In the capacitive method (bipolar, tripolar or multipolar electrode), energy alternates between 2 electrodes situated in a short distance from one another. In the tripolar and multipolar devices, bipolar energy switches between different poles at every moment. The energy is concentrated at the site of treatment and the achieved depth is half of the distance between the two electrodes.

In relation to temperature, it is common to find in the manuals of Brazilian and international equipments that the temperature required for stimulation of collagen synthesis ranges from 50° C to 75° C in the dermis, and that this temperature is reached when the epidermis remains at 40° C. However, when looking for studies to substantiate this information, they do not explain this affirmative, leaving doubts about the veracity of the information. Another issue observed is that with the use of international equipments patients need to receive anesthetics to withstand the temperature rise. In the manuals of Brazilian equipments, however, this fact is not mentioned, despite the need to achieve the same therapeutic temperatures. International equipments have a cooling system that protects the epidermis while the dermis is heated and Brazilians devices do not use these systems.^{13,80}

The results of this review showed that RF, despite being a commonly used procedure in clinical practice, still needs further study, with analyzes that have both methodological relevance and significant

statistical results. Despite the large number of papers on this, most have low methodological quality. According to the literature, good scientific evidence supports the use of new techniques -a fact not found in the present review on RF and skin laxity.⁸¹

CONCLUSION

This review allowed to observe that RF acts mainly with the purpose of promoting changes in tissue conformation, inducing neocollagenesis by thermal generation in deep layers of the skin tissue, thus being theoretically suitable for the treatment of wrinkles and skin laxity.

There are a large number of studies being carried out on this subject. However, most studies are not clinical trials with good methodological quality, which prevents decision-making about the effectiveness and the actual role of RF in the treatment of wrinkles and skin laxity.

It is possible that equipments used so far promote the benefits commonly reported by clinical perception. However, if they do occur, mechanisms to explain them are still unknown in scientific circles.

Parameters for adjustment of physiological and therapeutic effects are needed, however the reviewed articles are not clear on the data about temperature as well as the way of measuring the target tissue, the dermis. While there are studies demonstrating the effects of RF, there is a lack of studies specifying the most suitable parameters, especially with respect to power for different tissues. In general, the protocols reported in the literature vary considerably, making definitive conclusions about the most effective parameters extremely difficult.

The use of RF has been based more on marketing than on technical-scientific reasons, as there are a large number of devices available on the market and this number increases every day, without studies with good levels of evidence being carried out. Experimental studies are needed to make an accurate correlation between the temperature of the epidermis and dermis in order to further clarify the effectiveness of RF for the treatment of skin laxity, especially with Brazilian equipments.

Based on the data exposed, it is clear that using RF for the treatment of skin laxity is still a myth to be clarified and its use should therefore be cautious in the professional practice, especially when the parameters are out of the recommended specifications.

Footnotes

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