

## ORIGINAL ARTICLE

# Vacuum and electromagnetic field in synergy for skin rejuvenation: A retrospective study on 217 patients

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## Abstract

**Background:** There are many aesthetic treatments aimed at combating aging. In the most common and frequently used ones there are often side effects, albeit minor ones. However, sometimes it is necessary to use medications before or after treatments.

**Objectives:** To evaluate the anti-aging efficacy and application safety of a therapy based on the combination of vacuum and electromagnetic fields (EMFs).

**Methods:** A retrospective study was conducted to evaluate the aesthetic effects of the treatment on 217 subjects. Before treatment (T0) and after the last session (T1), skin hydration levels, the amount of sebum present and the pH were measured. The presence of discomfort during the sessions and side effects at T1 was verified. At T1, the levels of satisfaction of the patients and of the doctors who performed the treatment were assessed. At 3 and 6 months of follow-up the aesthetic results were re-evaluated.

**Results:** For all treated subjects, an evident qualitative improvement was observed in the quality of the skin of the neck and face, with an increase in tone and a reduction in wrinkles. The instrumental tests highlighted a normalization of skin hydration, pH, and sebum values. High levels of satisfaction at T0 and good stability of results up to 6 months of follow-up were reported. No discomfort was referred during the treatment sessions, nor any side effects after the entire treatment.

**Conclusions:** The treatment that exploits the synergy between vacuum and EMFs is very promising given the effectiveness and safety of the technique.

## KEYWORDS

aging, Biodermodermogenesi, electromagnetic field, regenerative medicine, vacuum

## 1 | INTRODUCTION

Parallel to the increase in social well-being and the average life span, requests for aesthetic treatments have also increased, primarily face, and neck rejuvenation. In medicine, there are many

treatments used to combat skin aging. In addition to injections and topical therapies, various methodologies based on different types of medical devices have been consolidated. The most common are needling, radiofrequency (RF), laser and focused ultrasound (fU).

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Needling is performed using devices equipped with microneedles, which create micro-lesions on the skin, triggering the stimulation of the fibroblasts present in the dermis. Consequently, the fibroblasts produce collagen and elastin, in an induced process of natural skin regeneration. Needling side effects are generally limited to short-lasting erythema and edema.<sup>1,2</sup> It rarely caused hyperpigmentation, localized superficial infections, allergic reactions.<sup>1-3</sup> Topical antibiotic therapy may be prescribed based on skin reaction.<sup>3</sup>

The RFs used for anti-aging treatments are non-ablative. They can be monopolar or bipolar, depending on whether they are applied to the surface, or through intradermal needle-electrodes.<sup>4</sup> They can also be resistive or capacitive, but the former is preferred because it allows better control of the temperature variation. The resistive RF (rRF) is supplied as high frequency alternating current through one or more conductors applied to the skin, called "poles". This energy passes through the skin tissue, which is transformed into an electrical resistance, and tends to overheat quickly and intensely. This phenomenon called "thermalization" leads to the denaturation of collagen and a consequent repair drive. The use of RFs generally leads to non-persistent episodes of erythema and edema.<sup>4,5</sup> In addition, the treatment is perceived as painful by many patients. Out of 25 patients treated with superficial rRF, Riuz-Esparda found painful sensations during treatments in 13.64%.<sup>6</sup> In a study by de Felipe et al, of 290 patients treated with intradermal rRF, 9.3% experienced intense pain during treatment, and 6.22% reported second degree burns.<sup>5</sup> Antibiotic prophylaxis is indicated for intradermal RF.<sup>7,8</sup> In superficial RF, the use of antibiotics is necessary in case of burns from contact with the surface electrode.<sup>9</sup>

Lasers are divided into non-ablative or ablative depending on whether their action involves only the lower layers of the skin or even the outer surface. The CO<sub>2</sub> laser (10600nm) and the erbium laser (Er:YAG; 2940nm) are ablative lasers, and are used for deep treatments. Non-ablative lasers perform softer treatments than ablative lasers, but are widely used in rejuvenation treatments. Among them are the Q-switch lasers, which are the ruby laser (694nm), the alexandrite laser (755nm) and the Nd: YAG laser (aluminum garnet and neodymium yttrium; 1064 or 532nm). Other non-ablative lasers are the pulse-dye laser (PDL; 585–595nm), the diode laser (800–980nm), the KTP laser (potassium-titanium-phosphate; 532nm). Both ablative and non-ablative lasers can be fractionated and non-fractionated. The former during the treatment leave microscopic columns of untreated tissue in the treatment area, to help limit the temperature increase. The laser beam is collimated and acts on individual skin components, in particular hemoglobin and water. Thermal micro-damage of the coagulation type is induced, and repaired through the production of new cells and, above all, collagen. Although the use of fractional tools increases the safety margin of treatments, side effects ranging from mild to severe have been reported.<sup>10</sup> Among the mild complications, the most common are the appearance of milia (19%), acne (2%–10%) and erythema (1% non-ablative laser; 12.5% ablative laser with persistence of symptoms for up to 3 months). Among the moderate complications, the most common is infection (0.3%–2%). Other complications are rare. Especially

following the onset of acne and infections, the use of antibiotics may be necessary and these should be used as prophylaxis if other treatment sessions are planned.<sup>10</sup>

In fU, the thermal shock produced inside the tissue causes mini-coagulation points at the level of the middle and deep reticular layer of the dermis and hypodermis. Consequently, a reparative action is triggered. The main limitation of this technology is the pain felt by patients during treatment, which sometimes involves the use of anesthetics.<sup>11,12</sup> Side effects associated with this method are mild and are mainly transient erythema, edema, and bruising.<sup>11,12</sup> Less common effects are the appearance of skin streaks,<sup>11,12</sup> wheals, post-inflammatory hyperpigmentation, muscle weakness, transient numbness.<sup>12</sup> Trigeminal or mandibular motor nerve palsy is rare.<sup>11</sup>

What binds all the procedures described above, except needling, is the thermal shock that is induced at the level of the middle and deep layers of the skin. The effects related to thermal shock can persist even up to 7 days after treatment, spreading beyond the directly targeted area.<sup>13</sup> This can be positive because it shows that the healing process continues after the acute phase of the treatment and covers a larger area than the target area.<sup>13</sup> But the thermal effect on healthy tissues, if not controlled, can compromise their vitality.<sup>14,15</sup> Some treatments are able to induce thermal rises that can liquefy the collagen beyond any possible contraction,<sup>12,15</sup> preventing the beginning of the healing and tissue regeneration phase. These increases can also be linked to an incorrect duration of skin exposure, caused by the prolonged duration of treatments.<sup>15</sup>

The aim of this study is to evaluate the efficacy and safety of a non-invasive technology that combines the application of vacuum and the irradiation of an electromagnetic field (V-EMF), verifying its action through the detection of some skin parameters, and evaluating the presence of side effects.

## 2 | MATERIALS AND METHODS

We performed a retrospective chart review of 217 patients scheduled for aging treatment in 2021. All subjects had not received other antiaging treatments in the 3 months prior to initiation of V-EMF therapy. In conjunction with this one, they did not perform any other anti-aging treatments. In the 24 h preceding each single V-EMF treatment session they had not used any cosmetic product. The study was conducted in full compliance with the ethical norms and standards in the Declaration of Helsinki. An informed consent statement was obtained from all the subjects.

### 2.1 | Patients

The patients ranged in age from 35 to 81 years. The treatment was performed on a greater number of women than men (185 females; 32 males). A more detailed characterization by gender and age is shown in [Table 1](#). All subjects considered had skin phototype IV.

All patients were healthy subjects with intact skin. The subjects were selected on the basis of the application limits of the V-EMF method, which are: pacemaker bearers, epileptics, people with severe skin inflammation, subjects with wounds that have not completely healed, subjects who have undergone oncological therapy in the last 5 years, subjects who have suffered from anorexia or bulimia in the past 2 years.

## 2.2 | V-EMF therapy

A detailed description of the principles underlying this therapy is given by Veronese et al.<sup>16</sup> For the anti-aging on the face, the therapy was carried out using the Bi-one® Life Touch Therapy device (Expo Italia Srl).

The electromagnetic field (EMF) was generated by applying a capacitive RF (cRF). Unlike rRF, cRF does not deliver energy directly to the patient's skin. A high-frequency signal is directed to a specific "shielded electrode", that is, an electrode whose outer part is covered by an insulating shield (dielectric material). The application electrode and the deep structures of the skin, separated from the electrode shield and tissues with insulating properties (such as the epidermis) form a capacitor, in which the action of the EMF takes place. A flow of positive ions (including sodium, Na<sup>+</sup> and potassium, K<sup>+</sup>) moves into the underlying tissue of the epidermis, crossing cell membranes and delivering nutrients to the cells. The inversion of the electric charge determines the opposite action in the cells, with an increase in the catabolic fluxes. These actions are due to the magneto-mechanical effect induced by the therapy, an effect which is linked to the piezoelectric properties of the tissues, that is, their ability to alter their own structure in response to magnetic stress. The connective tissue of the skin has important piezoelectric properties and its structural deformation, induced by EMFs, favors the rebalancing of the extracellular matrix (ECM).

Furthermore, the electromagnetic waves determine the movement of the ions present in the skin tissue, that is, the development of a kinetic energy. Part of this energy is transformed into thermal energy, and determines an endogenous diathermic effect. This leads to a slight heating of the dermis, which allows tissue regeneration and an increase in clearance, according to Van't Hoff's law. In fact, an increase in metabolic reactions is determined, with an increase in the microcirculation, and in the number of gaseous exchanges between blood and tissues. The results are: a more rapid drainage of catabolites associated with a "cell kill" effect of

senescent and/or damaged cells, and an increase in the diapedesis of granulocytes, macrophages and cells involved in inflammatory and reparative processes. At the tissue level, there is relaxation of muscle contractures and an increase in the elasticity of the connective tissue.

Unlike other technologies based on EMF where the output frequency is fixed, Biodermogenesi® uses a variable frequency from 0.5 to 2MHz and an average power between 4 and 6W, automatically regulated by a biofeedback system. The amount of energy absorbed by the skin is constantly calculated to ensure that the induced thermal excursion does not lead to increases in tissue temperature above 39°–40°C.

The application of electromagnetic waves in a vacuum amplifies tissue reactions, with consequent activation of endothelial cells, fibroblasts and skin myofibroblasts. The vacuum was supplied at 100–150 millibars. This pressure allows the skin tissue to dilate by one millimeter and, consequently, mechano-transduction is activated, that is, the conversion of mechanical stimulation into biochemical signals,<sup>17</sup> which determine a metabolic, catabolic, and regenerative reaction of the tissues in which these signals propagate.

## 2.3 | Treatments

All subjects underwent five treatment sessions on the face and neck. Usually the Biodermogenesi® method involves performing a weekly treatment session or two sessions a week, depending on the skin type of the individual subject.

A neutral alcohol-based cleanser was used on the skin before starting the procedure. Subsequently, the handpiece of the device was positioned on the skin and slid over the face and neck, to guarantee uniformity of action on the whole area. The duration of each single session was 20 min.

At the end of the treatment, no protective, soothing, or moisturizing products were applied to the skin.

## 2.4 | Analysis

Before the treatment (T0) and after the last session (T1), skin hydration levels, the amount of sebum present and the pH on the forehead, cheeks, and chin were measured. The measurements were carried out using the instruments Corneometer CM825 (Courage+Khazaka electronic GmbH, Köln, Germany), Sebumeter SM810 (Courage+Khazaka electronic GmbH, Köln, Germany), and skin pH-meter PH 900 (Courage+Khazaka electronic GmbH, Köln, Germany). Anatomically, the exact points of the survey were:

1. the central point of the forehead from the glabella to the hairline;
2. considering the line of junction of the ala of the nose with the tragus, the point at 1/3 of lateral distance from the ala, bilaterally;

TABLE 1 Gender and age of the patients.

Age (years)	Females	Males
≤40	30	8
41–50	43	14
51–60	57	10
61–70	37	0
≥71	18	0

3. the central point of the chin.

These points correspond to points 2, 18, and 26 described by Voegeli et al.<sup>18</sup>

A comparison was made between the values recorded at T0 and T1, and with the values of optimal skin condition. The Wilcoxon signed-rank test was used for the analysis, with significance for  $p < 0.05$ .

The impressions of the patients during the treatment sessions were collected (no sensation, comfortable, uncomfortable, painful treatment), and the side effects recorded after the individual sessions and at the end of the entire cycle.

Furthermore, at T1 the levels of satisfaction with respect to the aesthetic effects, after the entire treatment, of both the doctors who performed the treatments and the patients were evaluated using a 5-point Likert scale (I=no improvement, II=slight improvement 1%–25%, III=moderate improvement 26%–50%, IV=good improvement 51%–75%, V=very good improvement 76%–100%), named Likert scale A. At 3 (T2), and 6 (T3) months of follow-up, the aesthetic results of the treatment were re-evaluated by the doctors who performed it using another 5-point Likert scale (I=marked attenuation of the results  $\geq 21\%$ , II=attenuation of results 11%–20%,

III=moderate attenuation of results  $\leq 10\%$ , IV=unchanged/stable results, V=improvement of results), named Likert scale B.

### 3 | RESULTS

In all the subjects considered there was an overall increase in skin tone with tighter skin, and an improvement in the appearance of the wrinkles present, which were less deep. These results appeared evident already at time T1, as highlighted in Figure 1.

The values of the levels of hydration, the amount of sebum present and the pH are shown in Table 2. An overall increase in skin hydration levels, a reduction in the amount of sebum present and a rebalancing of pH levels were found in all three areas tested. All three parameters were characterized by an initial situation of alteration, which normalized on average at the end of the treatment. For all subjects, in fact, normalization of skin hydration levels was highlighted, while for some subjects who started from a significant alteration of sebum production (in excess) and with a particularly basic pH, the levels improved, remaining however slightly outside the normal range.

As regards the impressions of the patients during the individual treatment sessions, they reported a pleasant feeling of warmth when



**FIGURE 1** Aesthetic results obtained after the last session of treatment (T1) at three independent clinics. In all 3 cases there is a general improvement in skin tone and a reduction in wrinkles. (A) Profile of the lower third of the face of a 56-year-old female before the treatment (courtesy of Dr. Fulgione's archive). (B) Profile of the female in (A) after the treatment. The profile of the jawline and neck is defined and plumped (courtesy of Dr. Fulgione's archive). (C) Frontal view of the chin and neck of a 48-year-old female (courtesy of Dr. Alberti's archive). (D) Frontal view of the chin and neck of the female in (C) after the treatment. Correct repositioning of the platysma is appreciated (courtesy of Dr. Alberti's archive). (E) Frontal view of the lower third of the face of a 81-year-old female (courtesy of Dr. Laura's archive). (F) Frontal view of the lower third of the face of female in (E) after the treatment. Both perioral wrinkles and marionette lines appear less defined, with skin tighter (courtesy of Dr. Laura's archive).

TABLE 2 Skin parameters pre- and post- the entire treatment.

Skin parameters	Normal value range	Site	T0	T1	Net variation	Perceptual variation (%)
Hydration levels	50–70	Forehead	43.55	58.24	+14.69*	+33.73*
		Right cheek	41.55	59.80	+17.93*	+43.92*
		Left cheek	42.35	60.20	+17.85*	+42.15*
		Chin	42.55	52.08	+9.53*	+22.4*
		Mean	42.55	57.60	+15.05*	+35.37*
		(min-max)	(32,72-47,15)	(50,96-61,19)		
Amount of sebum	100–130	Forehead	150.32	129.86	-20.46*	-13.61*
		Right cheek	146.74	128.18	-18.56*	-12.75*
		Left cheek	145.58	127.89	-17.69*	-12.15*
		Chin	147.36	128.79	-18.57*	-12.6*
		Mean	147.50	128.68	-18.82*	-12.76*
		(min-max)	(135,12-151,61)	(122,17-131,65)		
pH levels	5.5–6.5	Forehead	7.36	6.54	-0.82*	-11.14*
		Right cheek	6.94	6.41	-0.53*	-7.64*
		Left cheek	6.97	6.44	-0.53*	-7.6*
		Chin	7.45	6.53	-0.92*	-12.35*
		Mean	7.18	6.48	-0.7*	-9.75*
		(min-max)	(6,62-7,48)	(6,22-6,82)		

\* $p < 0.05$  in Wilcoxon signed-rank test.

sliding the handpiece, with an effect that lasted for a few hours after the end of the sessions.

No side effects were reported, neither in the short term (after each session), nor in the medium term (1 month after the end of the entire session cycle). It was also observed that the treatment sessions were not followed by downtime, that is, that all subjects immediately resumed all their activities, without any limitation.

The levels of satisfaction with the aesthetic results obtained at T1 are shown in Table 3.

Re-evaluations of doctors who performed treatments at 3 and 6 months are reported in Table 4. These re-evaluations were performed on 112 of the initial patients. Among these subjects, 12 had persistence of results up to 3 months of follow-up. All 12 subjects were <50 years old (8 were <40 years old, 4 were 41–50 years old).

## 4 | DISCUSSION

In evaluating the efficacy of V-EMF therapy, two substantial aspects emerge. First, the aesthetic, clinical, and functional results. Second, the absence of side effects during treatment, and in the short and medium term.

As far as effectiveness is concerned, the synergy of vacuum and EMFs induced by cRF has already been tested in various applications.<sup>19–23</sup>

Aesthetic improvement was evidenced in stretch marks, with reduction of visual stigmatization of both striae rubrae and albae.<sup>19,20,22</sup>

A profound action at the level of the ECM has been demonstrated. Neo-activation of melanocytes has been observed following exposure to the sun.<sup>20</sup> This reaction was previously absent. Furthermore, an overall restructuring of the collagen and elastin fibers was found, with a rebalancing of the tensile properties.<sup>19,22</sup>

Similar results have been described in scar treatments.<sup>21,23</sup> In addition to the reduction of visual stigmatization, the rebalancing of the physical-mechanical properties of the skin was measured, synonymous with restructuring of the ECM.

Finally, an increase in skin firmness and a rebalancing of collagen and elastin fibers in the ECM were observed in skin ptosis.<sup>19</sup>

The rebalancing of the ECM fibers, with the reactivation of the metabolic and catabolic activities, and the regeneration linked to the activation of the stem cell niche, are the basis of all anti-aging therapies. Therefore, the result obtained in the present study could almost be defined as obvious. In reality, the vacuum and electromagnetic emissions calibrations are independent, but closely related to the achievement of the objectives. For example, an excessive increase in temperature, linked to too strong magnetic fields, could not only impede the regenerative action, but even worsen the tissue texture, with the formation of fibrotic layers and/or cellular apoptosis.

In all the aforementioned studies,<sup>19–23</sup> which include more than 1000 subjects treated with V-EMF for various problems, the absence of distress during the treatment sessions was reported and no side effects were reported, both in the short and medium term. This is a particularly interesting data, especially when compared with the data of the most widespread anti-aging treatments.



TABLE 3 Levels of satisfaction at T1.

Likert scale A levels	Patients' satisfaction		Doctors' satisfaction (referred to individual patient's improvements)	
	Number of subjects	Percentage of subjects (%)	Number of patients	Percentage of patients (%)
I	0	0	0	0
II	0	0	0	0
III	19	8.8	18	8.3
IV	60	27.6	46	21.2
V	138	63.6	153	70.5

TABLE 4 Doctors' evaluation related to the stability of individual patient results, at 3 and 6 months of follow-up.

Likert scale B levels	Doctors' evaluation (related to the stability of individual patient results)			
	3 months of follow-up		6 months of follow-up	
	Number of patients	Percentage of subjects (%)	Number of patients	Percentage of patients (%)
I	0	0	7	6.2
II	4	3.6	72	64.3
III	10	8.9	28	25.0
IV	86	76.8	5	4.5
V	12	10.7	0	0

The pleasantness of the V-EMF treatment contrasts with the painful states of the treatments with rRF<sup>5,6</sup> and with fUs.<sup>11,12</sup> For the latter, the use of anesthetics may even be necessary, but the pre-treatment administration of diazepam is also widespread.<sup>12</sup>

Side effects are always described for needling, rRF, laser and fU, and among these the most common, although not serious, is erythema.<sup>1,2,4,5,10-12</sup> However, the variety of side effects is very wide and may be such as to require the use of antibiotics.<sup>3,9,10</sup> In infra-dermal RF, their prophylactic use is even recommended.<sup>7,8</sup>

The fact that it is necessary to resort to the use of drugs, such as anesthetics and anxiolytics, to make the treatment bearable for patients, and drugs, such as antibiotics, to resolve situations created by the treatment, may be the subject of discussion. In fact, these are all procedures performed for purely aesthetic purposes. Therefore, the use of drugs should be severely limited. In this sense, the data on V-EMF therapy are very encouraging. It seems to overcome these problems, given that neither in the current study, nor in previous studies,<sup>19-23</sup> did any subject have to resort to the use of pre- or post-treatment drugs.

A possible limitation of this study derives from the fact that specific measurements of skin elasticity, an important parameter for the analysis of skin rejuvenation, were not performed. However, given that skin hydration levels are strongly correlated with skin elasticity,<sup>24</sup> the improvement recorded in hydration levels can be considered an indirect index of the improvement in the degree of elasticity.

Nevertheless, direct measurement of this parameter will also be performed in further studies.

Finally, the data on the duration of the effect of V-EMF therapy are extremely interesting. Only 7 of 112 subjects had >21% worsening of outcomes at 6-month follow-up. Twelve out of 112

subjects even showed a progressive improvement up to 3 months of follow-up, to underline how profound the action of the therapy is on the tissues. It should be noted that it is not surprising that all of these 12 subjects were <50 years old, given that the ability to react to a stimulus is undoubtedly greater in more intact tissues. However effective an anti-aging therapy may be, if applied to sclerotic tissue, it can improve the tissue's tone and consistency, but the effects can only be limited and will certainly have a shorter duration. This supports the increasingly widespread line of thought of anticipating the start of anti-aging treatments, to make them preventive and not restorative treatments.

## 5 | CONCLUSIONS

The results, both qualitative and quantitative, obtained with V-EMF therapy, lead to the conclusion that this procedure is effective. In fact, the synergy between vacuum and EMFs provides results comparable to those achieved by the main anti-aging technologies. Furthermore, the absence of both discomfort during treatment sessions, and post-treatment side effects, make it a very safe technique.

## AUTHOR CONTRIBUTIONS

Simona Laura, Giovanni Alberti, Annalisa Beatini, Elisabetta Fulgione and Claudio Urbani performed the research. Sheila Veronese, Pier Antonio Bacci, and Annalisa Beatini designed the research study. Simona Laura, Giovanni Alberti, Pier Antonio Bacci, Annalisa Beatini, Elisabetta Fulgione and Claudio Urbani analyzed the data. Simona Laura, Sheila Veronese, Pier Antonio Bacci and Annalisa Beatini wrote the paper.

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## CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study (deidentified patients photographs, raw measurements of skin parameters for individual patients, and statistical analyses) upon reasoned request, from trained practitioners and dermatologists, from the corresponding author for 3 years after the publication of this study. The data are not publicly available due to privacy or ethical restrictions.

## ETHICS STATEMENT

Authors declare human ethics approval was not needed for this study. The study was conducted in full compliance with the ethical norms and standards in the Declaration of Helsinki. All the participants gave informed consent for the publication of their data.

## INFORMED CONSENT

All the participants gave informed consent for the publication of their data.

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